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OVERSIGHT OF IMMUNIZATION COST

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ORIGINAL

COMPLETED

HEARING

BEFORE THE

SUBCOMMITTEE ON INVESTIGATIONS AND GENERAL OVERSIGHT

OF THE

COMMITTEE ON LABOR AND HUMAN RESOURCES UNITED STATES SENATE

NINETY-SEVENTH CONGRESS

SECOND SESSION

ON

TO REVIEW FEDERAL AND STATE EXPENDITURES FOR THE PURCHASE OF CHILDREN'S VACCINES

JULY 22, 1982

Printed for the use of the Committee on Labor and Human Resources

U.S. GOVERNMENT PRINTING OFFICE

98-284 O WASHINGTON : 1982

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OVERSIGHT OF IMMUNIZATION COST

THURSDAY, JULY 22, 1982

U.S. SENATE,
COMMITTEE ON LABOR AND HUMAN RESOURCES,
SUBCOMMITTEE ON INVESTIGATIONS AND GENERAL OVERSIGHT,
Washington, D.C.

The subcommittee met, pursuant to notice, at 10:07 a.m., in room 1318, Dirksen Senate Office Building, Senator Paula Hawkins, (chairman of the subcommittee) presiding.

Present: Senator Hawkins.

Staff present: Jay Howell, chief counsel, Terri Parker, counsel; Tim Jenkins, Investigator; Lisa Demetree and Constance Winter, professional staff; and Joanne Glissen, minority staff.

Senator HAWKINS. Good morning. As usual, there are several committees meeting at the same time this morning. The Joint Economic Committee is meeting on the economic picture. Jack Kemp is scheduled to testify. I am a member of that committee, as is Senator Kennedy. He is there now and may come in for this hearing later.

On May 7, 1982, this subcommittee held oversight hearings on the U.S. immunization program. At that time we heard about the tremendous progress that has been made in the last 20 years in attempts to eliminate preventable childhood diseases. We learned that measles and polio, once regarded as dangerous and crippling inevitabilities of childhood, have been nearly eliminated. Other diseases such as mumps, pertussis, diphtheria, and rubella are also on the decline. Remarkably, this has all been accomplished at a tremendous net resource and fiscal savings to this country. This is cost-effective, preventive medicine, and I remain committed to insuring the program's continued success.

At the May 7 hearing, we were also told that increased vaccine costs threaten this program. Quite simply, these dramatic increases will mean that fewer children will be immunized. Representatives of the Centers for Disease Control [CDC] in Atlanta testified that the price of the measles-mumps-rubella vaccine, which is called MMR on our charts around the room, increased 44 percent last year. The price for the polio vaccine, also purchased by the CDC for State use, increased 20 percent last year. Over the last 5 years, polio and MMR vaccine prices have nearly doubled despite the fact that the rate of inflation was only 50 percent. This is illustrated in charts I and II.

[The charts referred to follow:]

Senator HAWKINS. On May 7, we asked why these prices had increased so dramatically, and Dr. Hinman, the Director of CDC's Immunization Division, responded, quote, "One would have to ask the manufacturer." Unfortunately, Dr. Hinman was right. Since then we have asked appropriate State and Federal officials if they understood why they were paying so much more for the vaccine. They had no explanation for the increases, and so we went to the manufacturers. They discussed with us their reasons for the price increases and their experience in the vaccine production business. I am not convinced that all the questions have been answered. We hope to complete that process today.

A significant cause of my continued concern is that the vaccines at issue today are bought and sold on the international market at a fraction of the U.S. price. This is shown on chart III. The disparities are so great that they are not easily explained by traditional factors. While many manufacturers on the international market are foreign companies, U.S. manufacturers have also participated. We will discuss some disturbing examples of that today.

[Chart III referred to above follows:]

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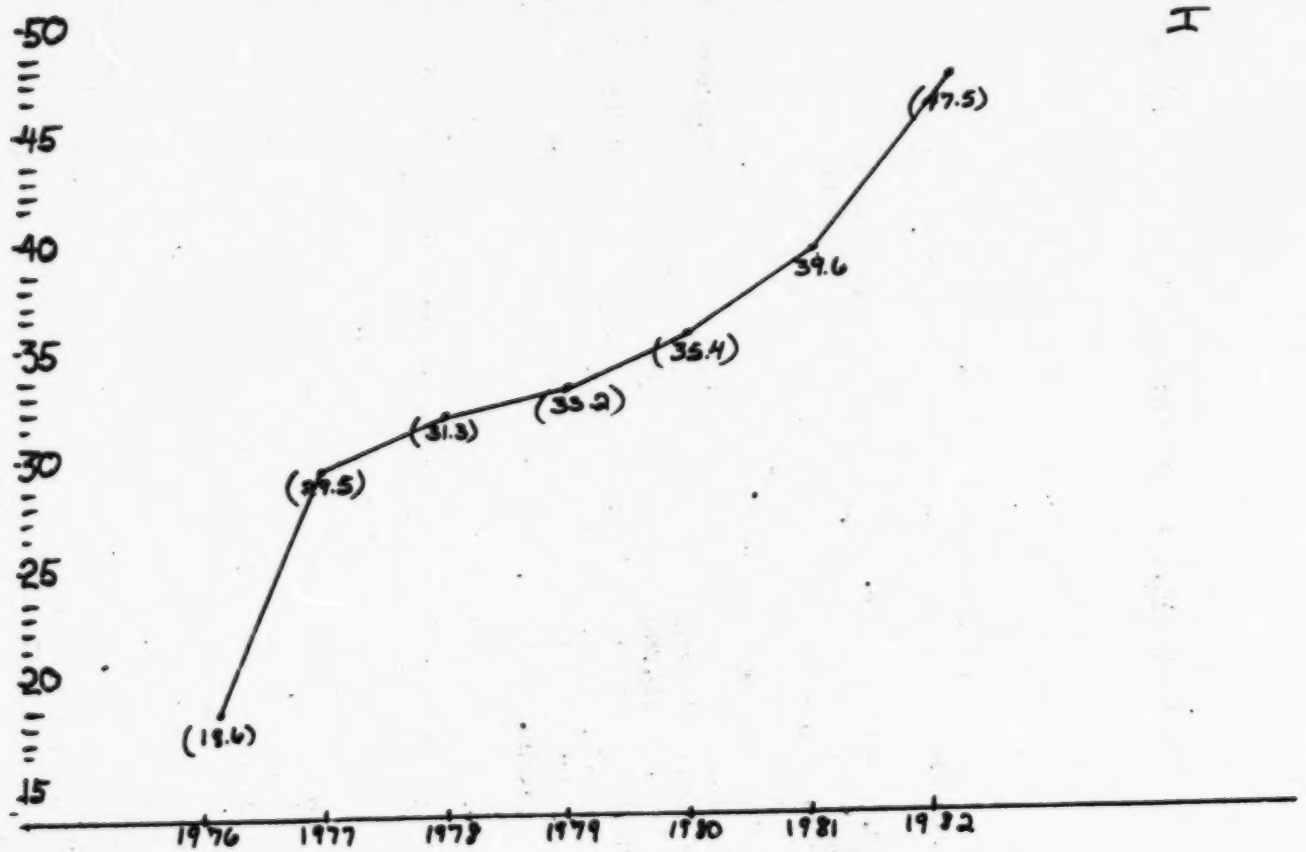
Federal (CDC) Polio Purchases (in cents)



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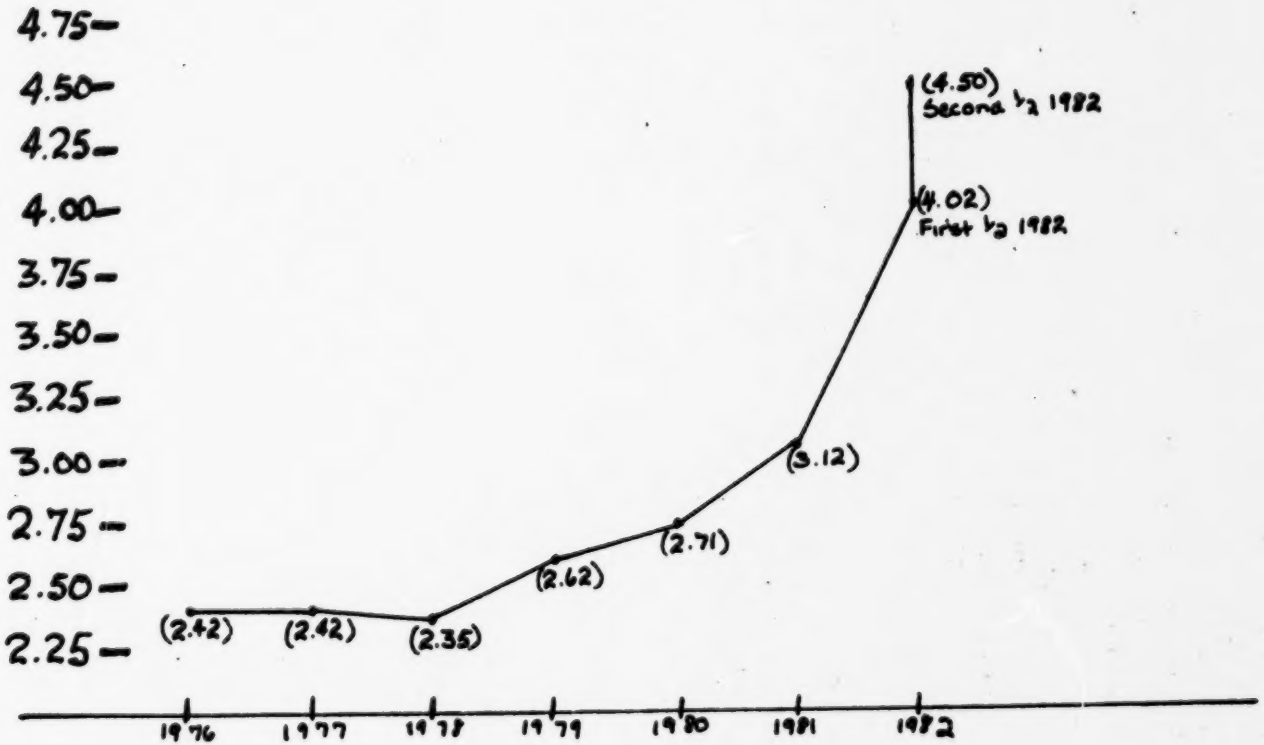
Federal (CDC) MMR Purchases

(in dollars)

II.



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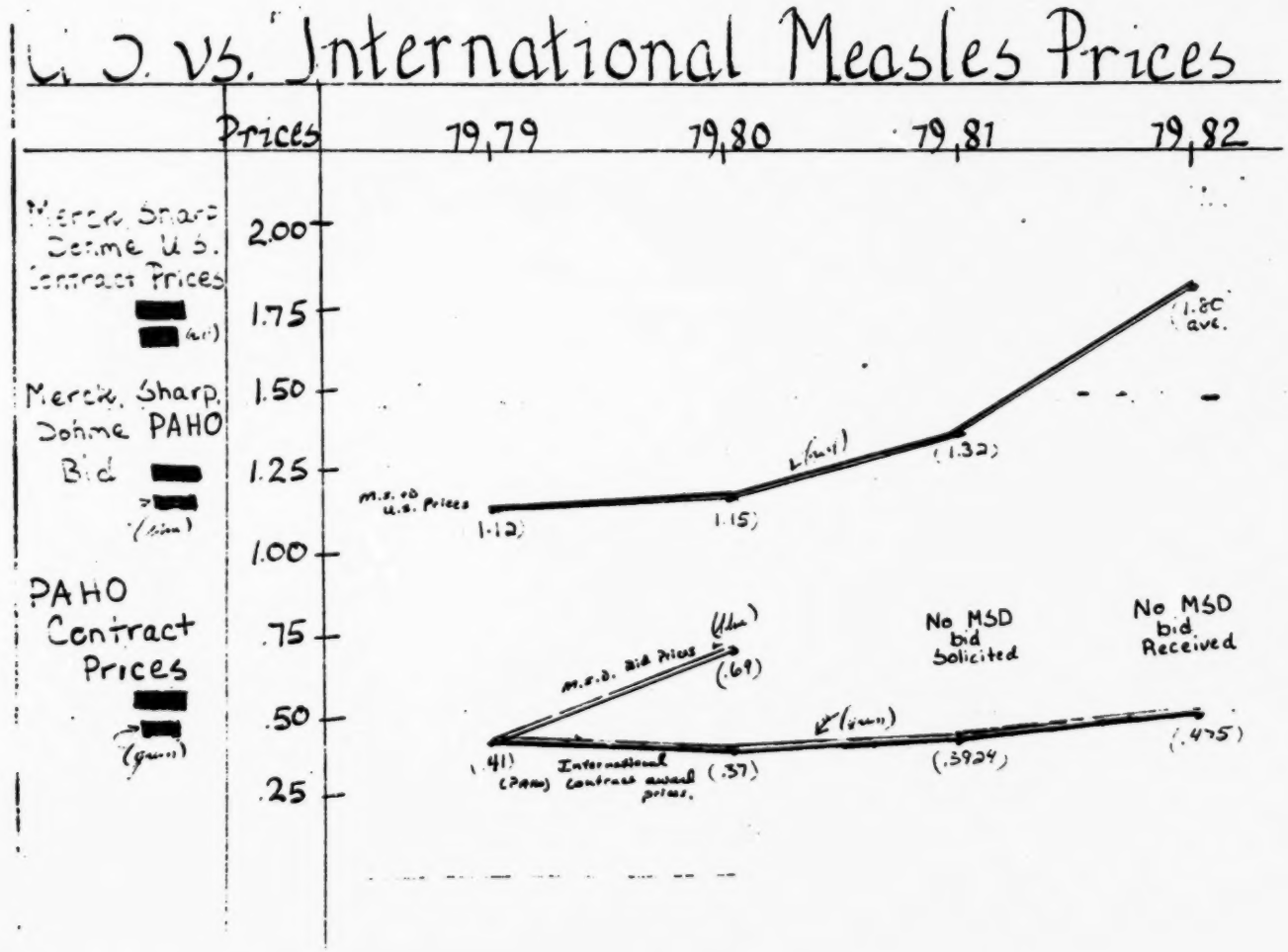

Senator HAWKINS. At the State level, we have encountered problems regarding program administration and vaccine purchase procedure. In most States, there appears to be little communication among immunization program personnel and their counterparts in purchasing who handle and approve vaccine bids. Often, the purchasing agents negotiate thousands of different contracts and do not have the time to distinguish among them. This may result in a higher price being paid or an inferior quality vaccine being procured.

In addition, we discovered that States do not communicate with each other regarding vaccine prices. This lack of communication adds to inexplicable price variations. As chart IV illustrates, in 1981, four States purchased the DPT vaccine from the same manufacturer at a price per dose of 12 cents, 14 cents, 15 cents, and 18 cents. The State that purchased the most doses paid the highest price per dose. None of them had consulted the other to compare the prices. In fact, none had ever discussed contract prices with the other States. Increased communication may enable State procurement officials to bargain for lower prices.

[Chart IV referred to above follows:]

Senator HAWKINS. At the State level, we also discovered examples of budget-juggling that resulted in high program costs to the States. In two States, the full complement of MMR and polio vaccines were not bought at reduced CDC prices. Instead, Federal funds were utilized for personnel, while State funds were used to purchase these vaccines at nearly twice the price. Because it did not take advantage of the CDC contract with the manufacturers which entitles States to reduced prices, one State alone paid over $1 million extra for vaccine over a 5-year period. The other example proved less costly—at least $80,000 over 2 years—because officials recognized the error and adjusted purchase procedure accordingly.

These examples are especially significant because Federal CDC employees were present in these States, at those times, working alongside State officials coordinating State programs. In the States mentioned above where funds were not expeditiously spent for MMR and polio vaccine, Federal CDC employees either were not aware of the situation, failed to report the matter, or did not feel it was even necessary.

I am concerned that the CDC, in its role as contract negotiator for MMR and polio vaccine, has not taken an active and aggressive role in confronting these serious cost increases. If satisfactory answers are not found, the CDC should advise the Congress and should begin consideration of alternative markets and means of stimulating competition. In order to preserve and protect this critical program, a great deal of effort and initiative may be required. The CDC is in the best position to provide that and should take the lead in these areas.

Competition in the marketplace is clearly the key ingredient to keeping the cost of vaccines down. Because the domestic polio and measles-mumps-rubella vaccine markets are sole-source, efforts to avoid wasteful practices and poor management at both State and Federal levels must be redoubled. The manufacturers of these vaccines are taking full advantage of a profitable business situation. Until market forces are developed to bring these prices down, the only factors working in favor of the States and the Centers for Disease Control are cooperation, communication, and efficiency. These must be utilized to the fullest.

For our first panel of witnesses today, I warmly welcome Dr. Jorge Litvak, chief of the division of disease prevention and control of the Pan American Health Organization, and his colleagues, Dr. Henry Cooney, special assistant to the chief of administration; Mr. Walter Umstead, chief of procurement; and Mr. Gaston Tawil, regional adviser of biologics. I thank you for appearing before this subcommittee today.

Dr. Cooney, would you please explain the procedure used by the Pan American Health Organization to purchase vaccine for member countries?

STATEMENT OF DR. HENRY F. COONEY, SPECIAL ASSISTANT TO THE CHIEF OF ADMINISTRATION, PAN AMERICAN HEALTH ORGANIZATION, WASHINGTON, D.C., ACCOMPANIED BY DR. JORGE LITVAK, CHIEF, DIVISION OF DISEASE PREVENTION AND CONTROL, PAN AMERICAN HEALTH ORGANIZATION; WALTER UMSTEAD, CHIEF OF PROCUREMENT, PAN AMERICAN HEALTH ORGANIZATION; AND DR. GASTON TAWIL, REGIONAL ADVISER, BIOLOGICS, PAN AMERICAN HEALTH ORGANIZATION

Dr. COONEY. Thank you, Senator Hawkins. As you said, I am Dr. Henry F. Cooney of the Pan American Health Organization. We would like to thank you for giving us this opportunity to testify before this committee on procurement of vaccines for the Pan American Health Organization's expanded program on immunization, which we call the EPI program.

Senator HAWKINS. Can you hear Dr. Cooney in the back?

Would you pull the microphone close to your mouth, please? We have a packed room and I would like everybody to hear your story.

Dr. COONEY. I will start again, Senator Hawkins.

I am Dr. Henry F. Cooney of the Pan American Health Organization. We would like to thank you for giving us the opportunity to testify before this committee on the procurement of vaccines for the Pan American Health Organization's expanded program on immunization, which we call the EPI program.

Let me first introduce myself and the three other PAHO staff members who have accompanied me. I am the special assistant to the chief of administration of PAHO. I have a master's degree in business administration, a master's degree in public administration, and a doctorate degree in public administration. I have served 35 years as an administrative officer and comptroller in the health field, including 10 years in administration in PAHO.

Dr. Jorge Litvak is the chief of the division of disease prevention and control of PAHO, with program responsibility for the PAHO immunization program. Dr. Litvak is a physician with an M.D. degree from the University of Chile Medical School, where he became the dean of the faculty after 20 years of academic activity. He is currently also a member of the University of Miami Medical School faculty in the department of epidemiology and public health.

Dr. Gaston S. Tawil is the PAHO regional adviser on quality control of biologics. Dr. Tawil is a physician with an M.D. degree, plus a doctorate degree in medical microbiology from Cairo University in Egypt. His experience includes 16 years teaching medical microbiology at Cairo University and 15 years in the development of laboratory services with the World Health Organization. Since 1978, he has been the PAHO regional adviser on production and quality control of biologics.

Mr. Walter Umstead is the chief of the procurement office of PAHO. He has a master's degree in business administration. He has served 29 years in supply management, including duties in procurement and contract administration. This experience includes 6 years as the chief of the PAHO procurement office.

I would like to briefly summarize the Pan American Health Organization and the PAHO expanded program on immunization.

The Pan American Health Organization is an international organization composed of 32 member governments in the Americas and three participating European governments with interests in the Western Hemisphere.

The Pan American Health Organization provides technical cooperation and coordination in the efforts of its member countries in the Americas to extend basic health services to its populations. Member governments have adopted the goal of health for all by the year 2000, based on an agreement that their main social target should be attainment by all citizens of a level of health that will permit them to lead socially and economically productive lives.

The governments have also agreed on minimum regional health goals to increase life expectancy, reduce infant mortality, provide immunization for all children against major diseases, supply safe drinking water and adequate sanitation, and extend access to health services to the entire population by the year 2000.

PAHO also serves as the regional office for the Americas of the World Health Organization. The EPI program is an essential part of our primary health care strategy and is a priority program of the Pan American Health Organization. The EPI goal is to provide immunization services for all children under 1 year of age and pregnant women in tetanus-endemic areas by the year 1990.

The program aims at assuring that immunization services are available against polio, measles, tetanus, diptheria, whooping cough, and tuberculosis—diseases which affect a high proportion of young children in Latin America and the Caribbean. Together, these six diseases kill millions of children each year worldwide. Each of these diseases may be prevented inexpensively and with a high degree of efficacy.

In order for countries to carry out an immunization program, it is necessary to purchase vaccines, syringes, needles, and refrigeration equipment for the storage and transportation of vaccines.

In January 1979, responding to the needs of countries wishing to participate in the expanded program on immunization, PAHO started operation of an EPI revolving fund for the purchase of vaccines and related supplies. The revolving fund establishes a reimbursement mechanism for purchase of the vaccines and related supplies in local currencies by member countries. The working capital for the fund is currently slightly in excess of $2,300,000. These moneys were made available from funds provided by the member governments and through voluntary contributions.

Prior to the establishment of the EPI revolving fund, PAHO was unable to coordinate vaccine procurements, nor could purchases be made until funds were deposited in advance of each request for vaccines. Each order had to be treated as an individual request, requiring bids and negotiations of delivery and other terms and conditions. This resulted in duplications of effort, delays of shipment, and higher costs.

In the case of urgent requirements, orders were placed solely on the supplier's ability to meet delivery without regard to price. Prices paid by countries were generally higher, since manufacturers were unable to plan their production in advance.

In order to assure that quality vaccines are available to all countries in the region, the EPI revolving fund has the following objectives:

First, to enable member countries of the region to program their immunization activities and procure their requirements for vaccines and related supplies in an orderly and continuous manner, thereby avoiding disruptions in their programing due to lack of vaccines or lack of immediate funds for their procurement.

Second, to permit countries to use local currencies instead of U.S. dollars to reimburse their vaccine purchases, thus avoiding delays and losses in the exchange of local currencies for U.S. dollars. PAHO uses these local currencies in its country programs to the extent possible.

Third, to consolidate vaccine requirements for all participating revolving fund members and to pass on to them benefits from the resulting economies of scale, including the procurement of vaccines at lower prices.

Fourth, to assure participating countries in the fund of a good supply of quality vaccines that meet PAHO–WHO standards.

Fifth, to establish contracts with suppliers of vaccines that allow urgent orders to be placed and delivered on short notice.

In 1979 when the program became operational, 20 countries participated in the program. The present membership of the fund includes 31 countries of Latin America and the Caribbean. During its first 4 years of operation, the EPI revolving fund will have placed orders for vaccines worth over $14 million.

Senator, this statement has been a brief summary of the PAHO EPI program. We feel that the PAHO Expanded Program on Immunization, using the revolving fund concept, has been successful and very beneficial to our member governments. We estimate that in recent years, not less than a 50-percent increase in immunization coverage has been achieved in the region. We hope to continue to improve our services to the member governments of our organization.

We will be glad to answer any questions which the committee may wish to put to us on this subject. Thank you.

Senator HAWKINS. Is there competitive bidding for all the vaccines you purchase?

Dr. COONEY. Yes, Senator, there is competitive bidding on all our purchases.

Senator HAWKINS. Do U.S. firms ever place bids for these?

Dr. COONEY. I would like to have, if you do not mind, our chief of procurement answer that particular question.

Senator HAWKINS. Anyone would be just fine.

Mr. UMSTEAD. Senator, I would like to add a few more comments to your first question.

Senator HAWKINS. On the procedure used for the purchase of vaccines?

Mr. UMSTEAD. I beg your pardon?

Senator HAWKINS. The procedure that you use to purchase?

Mr. UMSTEAD. On the procedure that we use to purchase.

We are dealing with five vaccines—measles, polio, DPT, tetanus toxoid, and BCG. We are purchasing for these 32 countries on a consolidated basis. Annually, we go out with this total requirement

and establish an annual contract with one or more suppliers for each vaccine. I would like to leave with you a copy of our invitation for bid as an example of how we go about this procurement.

[The invitation for bid follows:]

APO-EPI-1982

30 September 1981

Master '81

Gentlemen,

Enclosed is Invitation for Bid APO-EPI-1982 for the supply of vaccine to Pan American Health Organization (PAHO) Member Countries during the period from 1 January 1982 to 31 December 1982.

Bids will be received not later than 30 October 1981.

Sincerely,

Walter W. Umstead
Chief, Procurement

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SOLICITATION

VACCINES 1982

(1) Bids are solicited for the supply of vaccine to Pan American Health Organization (PAHO) Member Countries during a twelve-month period, from 1 January 1982 to 31 December 1982.

(2) Bids shall be received not later than 12 noon local time, on 30 October 1981 at:

Pan American Health Organization
525 Twenty-Third Street, N.W.
Washington, D.C. 20037
Attn: APO-EPI-1982

Telex 248338
Cable OFSANPAN

Bids shall be publicly opened at that time in the Procurement Office. Companies may be represented at the bid opening. An addressed envelope for submission of bids is forwarded herewith. Telex and cable bids will be considered if received prior to the opening of bids.

(3) All bids which comply with the terms of this solicitation shall be considered. Alternate bids shall be considered. PAHO reserves the right to reject any and all bids and to award contracts to more than one contractor for each vaccine.

(4) This solicitation does not commit PAHO to pay any costs incurred in the preparation or submission of bids or to procure or contract for supplies.

(5) All bids are subject to the following:

a) Schedule of Requirements
b) General provisions.

(6) Prices FOB supplier's airport shall be quoted in the Schedule of Requirements. Prices may be quoted in U.S. dollars or in the national currency of the supplier. Prices based on minimum quantities or quantity threshholds, or quantity discount or rebate arrangements will be considered.

(7) Standard packing information for each vial size of vaccine including diluent and syringes (if applicable), shall be [illegible] in the Schedule of Requirements to assist PAHO in [illegible] freight costs.

(8) Each bidder shall submit a signed Bid and Schedule of Requirements.

(9) The following shall accompany each bid:

a) Protocols on the method of production and control of each single and multiple antigens offered;
b) A sample of each vaccine in each vial size offered;
c) A sample of the vaccine vial label;
d) A copy of the instruction pamphlet or trade literature; and,
e) A technical description of the shipping container, including weight, cubic measurement, insulation and type of refrigerant to be used for each vaccine.

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APO-LPI-1982

SCHEDULE OF REQUIREMENTS

VACCINES 1982

Article 1. Scope of Contract

The contractor shall manufacture and supply the vaccine(s) listed in Annex 1 of the Schedule of Requirements in accordance with the Specifications and other terms and conditions set forth below during the contract period, to the countries and in the quantities specified in purchase orders issued by the Pan American Health Organization (PAHO), at the prices set forth in Annex 1.

Article 2. Period of Performance

The period of performance shall be 1 January 1982 to 31 December 1982.

Article 3. Specifications

A. Production and Testing

The vaccine shall be produced and tested in conformity with the following requirements established by the World Health Organization (WHO), and all revisions to these requirements issued by WHO:

i) General Requirements for Manufacturing Establishments and Control Laboratories (WHO Technical Report Series No. 323, 1966)

ii) General Requirements for the Sterility of Biological Substances (WHO Technical Report Series No. 530, 1973)

iii) Requirements for Diphtheria Toxoid and Tetanus Toxoid (WHO Technical Report Series No. 638, 1979, Annex 1)

iv) Requirements for Pertussis Vaccine (WHO Technical Report Series No. 638, 1979, Annex 1)

v) Requirements for Poliomyelitis Vaccine (oral) (WHO Technical Report Series No. 486, 1972)

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vi) Requirements for Measles Vaccine (live) (WHO Technical Report Series No. 329, 1966)

vii) Revised Requirements for Dried BCG Vaccine, Annex 2 (WHO Technical Report Series No. 638, 1979)

b. Licensure

The vaccine produced and delivered under this contract shall be manufactured under a current license issued by the National Control Authority. The contractor shall submit evidence of licensure to PAHO.

c. Protocols

The contractor shall submit with the bid a protocol of the method of production for each single and multiple antigens of the product to be supplied. A revised protocol(s) shall be submitted for technical review and approval by PAHO/WHO upon each change in seed used, production procedure, formulation, or presentation of the product being supplied. In the case of the attenuated poliomyelitis vaccine (oral), in addition to the above requirements, the contractor shall submit detailed protocols of the results of control, including those of the neurovirulence tests which were carried out on those monovalent bulks (Types 1, 2 and 3) that shall be used in the preparation of the trivalent vaccine. Vaccines supplied by the manufacturer shall be produced exclusively from those monovalent lots approved by PAHO/WHO.

Prior to the shipment of vaccine, the contractor shall submit to the PAHO/WHO unit on biologics a certificate of release from the National Control Laboratory as well as a summary protocol of results obtained by the contractor's control laboratory on the bulk vaccine and/or packaged vaccine of each lot of product being supplied. The special WHO forms issued for this purpose may be used (pro formas are available from PAHO or WHO on request). Shipment shall not be delayed pending review and clearance of protocols by PAHO/WHO. However, as indicated in Article 10, final acceptance of vaccine shipments shall be subject to technical clearance of production and control protocols by PAHO/WHO. A copy of the production and control protocol shall be forwarded with the vaccine shipment, if specifically requested in the purchase order.

d. Shelf Life

Fresh vaccine with the maximum shelf life attainable with current production technology shall be supplied.

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E. Presentation

Vaccine shall be presented in vial sizes as specified in Annex I.

F. Packaging and Labeling

i) The external surface of vaccine packaging shall be white. A label of the design specified in Figure 1 of Annex II shall be affixed to the outside face of each and every vaccine package and shipping container.

ii) Vial labels shall be fixed with water resistant adhesive. The expiry date shall be printed on each vial or vial label in indelible ink. Labels shall be in the language of the country of destination as specified in Article 6. Multilingual labels are acceptable. Labels shall state the lot number, composition, concentration, dose, expiry date and storage temperature.

G. Packing

i) Vaccine other than poliomyelitis shall be packed in containers suitable for export shipment and with adequate insulation and sufficient refrigerant to ensure that the storage temperature of the vaccine is maintained within a range of +4°C to +8°C during transit and for a period of at least twenty-four (24) hours after arrival at the airport of destination.

ii) Poliomyelitis vaccine shall be packed in containers suitable for export shipment and with polyurethane or similar insulation material of a thickness of not less than 50 mm and sufficient refrigerant to ensure that the storage temperature of the vaccine is maintained within a range of +4°C to +8°C during transit and for a period of at least twenty-four (24) hours after arrival at the airport of destination. If specified in the purchase order, poliomyelitis vaccine shall be shipped at -20°C and packed with sufficient refrigerant to remain at -20°C for at least twenty-four (24) hours after arrival at the airport of destination.

iii) The diluent for measles and BCG vaccines need not be cooled or shipped in insulated shipping containers.

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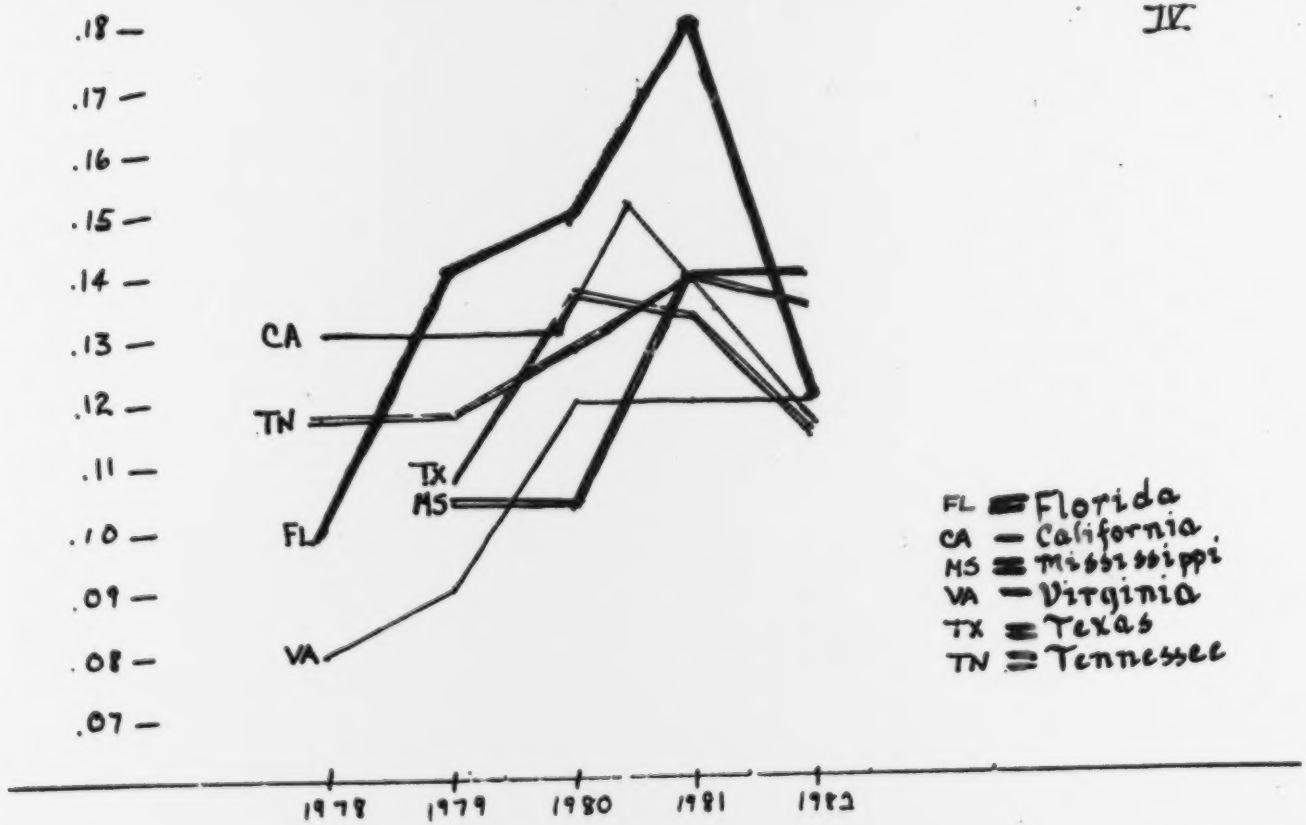
State Diptheria-Pertussis-Tetanus(DPT)Purchases

(in cents)

IV.



iv) Diluent shall be supplied in the same dosage size vial as the corresponding vaccine. Vaccine, diluent and syringes shall be packaged in cartons of uniform quantity content. Vaccine, diluent and syringes shall be booked on the same flight, if feasible.

v) Shipping containers insulated with less than 50 mm of polyurethane shall be subject to test and certification by a PAHO-designated testing laboratory as to the capability of the container to maintain the storage temperatures required in subparagraph G.(i).

vi) If specified in the purchase order, minimum/maximum thermometers shall be utilized to verify temperatures maintained in transit. The cost of the thermometers will be for the account of the Pan American Health Organization.

Article 4. Estimated Quantity

Estimated quantities of vaccine required for each quarter of 1982 are indicated in Annex 1. These estimates are based on Member Country plans for immunization in 1982. Estimates are subject to progressive revisions during the contract period.

Article 5. Quantity Guarantee

It is understood and agreed that during the contract period, PAHO will order vaccine only in the quantities required and as funded by the Member Countries. Estimates indicated in Annex I may or may not be reached or exceeded. PAHO does not guarantee to order a minimum quantity of any vaccine during the contract period. PAHO reserves the right to order up to and including the estimated quantity indicated in Annex I at the price specified, and to renegotiate the price for quantities in excess of the estimated quantity.

Article 6. Method of Ordering

Vaccines will be ordered by purchase orders, each citing as a minimum, the product, vial size, quantity and shipping instructions. Orders may be placed by telephone and will be confirmed in writing. To the extent possible, PAHO will place purchase orders prior to the start of the quarter during which the vaccines are to be delivered.

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Article 7. Time of Delivery

The bidder shall state, in the place provided in Annex 1, the definite number of days within which delivery will be made after receipt of a purchase order.

Article 8. Delivery Destinations

Member Countries for which PAHO expects to order vaccines during the contract period are listed below. The addresses of these delivery destinations are listed in Annex II.

Anguilla	(E)	Cayman Islands	(E)	Grenada	(E)	Peru	(S)
Antigua	(E)	Chile	(S)	Guatemala	(S)	St. Kitts	(E)
Argentina	(S)	Colombia	(S)	Guyana	(E)	St. Lucia	(E)
bahamas	(E)	Costa Rica	(S)	Haiti	(F)	St. Vincent	(E)
barbados	(E)	Dominica	(E)	Honduras	(S)	Suriname	(E)
belize	(E)	Dominican Rep.	(S)	Panama	(S)	Caicos & Turks	(E)
bolivia	(S)	Ecuador	(S)	Paraguay	(S)	Uruguay	(S)
						Venezuela	(S)

(E) = English-speaking (S) = Spanish-speaking (F) = French-speaking

Article 9. Terms of Delivery

A. The contractor shall ship vaccine to the destination indicated in the purchase order, by the most direct route. If transhipment is unavoidable, connections shall be scheduled in airports equipped with cold storage facilities. Instructions regarding storage temperature and re-icing required in transit shall be indicated in the Airwaybill.

B. In the case of certain destinations in the Caribbean Area, the contractor shall, if specified in the purchase order, ship the vaccine to a designated freight forwarder in Miami, Florida, for transhipment to the consignee and, if necessary, for arranging appropriate cold storage pending transhipment.

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C. The contractor shall book vaccine shipments well ahead of the date of departure. At least seventy-two hours prior to the scheduled departure of the shipment, the contractor shall cable flight details to the consignee and to PAHO in Washington, D.C. The telex or cable shall provide the following information:

1) Purchase order number
2) Type of vaccine
3) Deleted
4) Number of cartons
5) Gross weight in Kgs.
6) Flight number at final destination
8) Date of arrival at final destination
9) ETA at final destination
10) Airwaybill (AWB) complete number
11) The notation: "Please arrange immediate collection, or telex immediately if vaccines do not arrive."

D. Vaccine shipments shall be scheduled to arrive on Monday, Tuesday, Wednesday or Thursday only. Vaccines shall not be scheduled to arrive at destination during weekends or holidays, unless necessary to meet urgent delivery needs.

E. The following information shall be included in the Airwaybill:

1) Consignee's name, address and telephone number as provided by PAHO.
2) Type of vaccine and quantity;
3) The notation: "HIGHLY PERISHABLE, Telephone Consignee Upon Arrival: [Repeat telephone number]; and
4) The notation: "Medicines - Vaccine - For Human Use - Highly Perishable - Not To be Delayed - Connection by Booked Flight Pending Reshipment or Collection Store at +4°C to +8°C (35°F to 50°F) (or -20°C in the case of poliomyelitis vaccine shipped frozen)."

F. Two copies of the invoice or pro forma invoice with packing details shall be attached to the Airwaybill for customs clearance at destination. At the time of shipping, the following documents shall be sent to the consignee by airmail: (1) Copy of the Airwaybill, and (2) Copy of the invoice with packing details.

G. All invoices shall identify the vaccine lot numbers and the dates of expiry of the lots included in the shipment.

H. If requested in the purchase order, a copy of the production and control protocols shall be attached to the Airwaybill.

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Article 10. Acceptance

Final acceptance of vaccine shipments shall be subject to technical clearance of production and control protocols by PAHO/WHO and, if necessary, sampling by an authorized PAHO/WHO representative, for testing in the reference laboratory designated by PAHO/WHO. The decision of the reference laboratory shall be considered final.

Article 11. Price

Bidders shall indicate, in the spaces provided in Annex I or by an attachment, the prices for the vaccine they propose to furnish.

Article 12. Payment

Payment shall be made after receipt of contractor's invoice for all vaccines which have been accepted. Each invoice or voucher shall, as a minimum, identify the appropriate purchase order, type of vaccine, amount delivered, unit price and total price, and be accompanied by a prepaid international Airwaybill and evidence of insurance.

Invoices or vouchers shall be submitted to the following address:

PAN AMERICAN HEALTH ORGANIZATION
525 23rd. St. N.W.
Washington, D.C. 20037
ATTN: APO (purchase order number)

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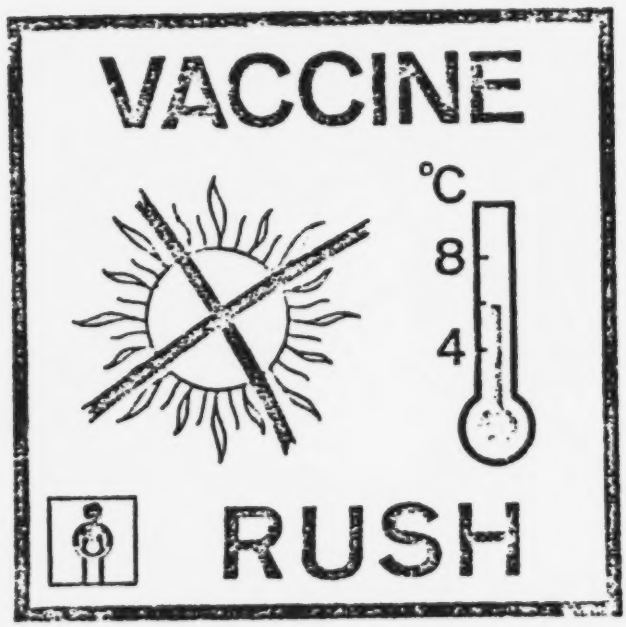
Figure 1. VACCINE SHIPMENT LABEL



ANNEX II

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APO-EPI-1982

GENERAL PROVISIONS

INDEMNIFICATION: The CONTRACTOR shall indemnify, hold and save harmless and defend at his own expense PAHO, its officers, agents, servants and employees from and against all suits, claims, demands, and liability of any nature or kind, including costs and expenses arising out of acts or omissions of the CONTRACTOR or his employees in the performance of this Contract. This clause shall extend to claims or liability in the nature of workmen's compensation claims or liability or those arising out of any claim or suit against PAHO, on account of any alleged patent or copyright infringement arising out of the performance of this Contract or out of the use of any supplies furnished for services performed hereunder.

DISPUTES: Except as otherwise provided in this Contract, any dispute concerning a question of fact arising under this Contract which is not disposed of by agreement shall be decided by the PAHO Contracting Officer, who shall reduce his decision to writing and mail or otherwise furnish a copy thereof to the CONTRACTOR. The decision of the Contracting Officer shall be final and conclusive unless within 30 days from date of receipt of such copy, the CONTRACTOR mails or otherwise furnishes to the Contracting Officer a written appeal to be referred to arbitration, the methods of such arbitration to be agreed between the contracting parties. The parties recognize that they are definitely bound by such arbitral decision. If no agreement can be reached concerning the appointment of the arbitrator, the dispute shall be finally settled under the Rules of Conciliation and Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with the rules.

TERMINATION: This Contract may be terminated by either party by written notice delivered to the other party at least 15 days before the effective date of termination. If the Contract is so terminated, the CONTRACTOR shall be compensated to the extent that PAHO shall be liable for payment for services rendered or to be rendered prior to the effective date of termination.

TITLE, COPYRIGHT, PATENT RIGHTS AND OTHERS: All rights, including title, copyright and patent rights to any material produced under the terms of this Contract shall be vested in PAHO, which shall be entitled to make whatever changes or eliminate whatever parts of the material it deems advisable.

CONTRACTOR RELATIONSHIP: In performing the services under this Contract, the CONTRACTOR shall have the legal status of an independent Contractor vis-a-vis PAHO. Neither the CONTRACTOR nor his personnel shall be considered employees or agents of PAHO. Unless otherwise provided for in this Contract, PAHO shall not be liable for claims of any kind including any loss, accident, damage or injury arising in connection with the performance of this Contract. It is also understood by the CONTRACTOR that he is not entitled to any income tax reimbursement for work performed under this Contract. The CONTRACTOR shall be responsible for his own travel arrangements (applications for passport and visas, customs requirements, etc.). The CONTRACTOR declares that on the date of signature of this Contract he is not a relative of any staff member of PAHO, and is not employed by the government of the country in which the services are to be performed.

STANDARD OF PERFORMANCE: The CONTRACTOR agrees that the services performed pursuant to the requirements of this Contract shall conform to the highest professional standards. The CONTRACTOR shall conform to all applicable laws, regulations and ordinances promulgated by legally constituted authorities of the government of the country in which the services are performed. Further, the CONTRACTOR agrees to utilize any information and/or documents obtained from or provided by PAHO for the purpose of this Contract exclusively for the activities agreed upon.

SUBCONTRACTING OR ASSIGNMENT: No services hereunder shall be subcontracted, nor shall any claim arising under or by virtue of this Contract be assigned, without the prior written approval of the PAHO Contracting Officer.

PAHO OFFICIAL NOT TO BENEFIT: The CONTRACTOR warrants that no PAHO staff member shall be admitted to any share or part of this Contract, or to any benefits that may arise therefrom.

PUBLICITY OR ADVERTISING: The CONTRACTOR shall not advertise the fact that such CONTRACTOR is a supplier of services to PAHO and or the World Health Organization. Also, the CONTRACTOR shall in no other manner whatsoever use the name, emblem, or official seal of PAHO and or the World Health Organization in connection with his business or otherwise.

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BID

In compliance with Solicitation APO-EPI-1982, the undersigned agrees, if this offer is accepted within 60 days from the date for receipt of bids specified therein, to furnish any or all items upon which prices are offered, at the price set opposite each item in Annex I of the attached Schedule of Requirements, delivered at the designated points, within the time specified in the schedule.

Name, Address and
Telephone Number

Name and Title of
Person Authorized to
Sign Bid

Date

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SCHEDULE OF REQUIREMENTS
VACCINES 1982

The contractor shall manufacture and supply the vaccines listed below in accordance with Articles 1 through 12 of the Schedule of Requirements at the prices and within the number of days indicated.

Vaccine: Measles

Vial Size	Price per Dose Quantity Total	1/2	1/4	Delivery Days ARO	Standard Packing Vials per Carton	Cartons per Container	Gross Weight Kgs. Per 1,000 plus refrigerant Vaccine	Diluent	Syringes
1*									
1									
10									

* with syringe (empty)

Estimated Quantities

Vial Size	Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec	Totals
1	1,570,000	450,000	1,470,000	440,000	3,930,000
10	1,439,000	850,000	460,000	350,000	3,090,000

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SCHEDULE OF REQUIREMENTS
VACCINES 1982

The contractor shall manufacture and supply the vaccines listed below in accordance with Articles 1 through 12 of the Schedule of Requirements at the prices and within the number of days indicated.

Vaccine: Polio

Vial Size	Price per Dose Quantity Total	1/2	1/4	Delivery Days ARO	Standard Packing Vials per Carton	Cartons per Container	Gross Weight Kgs. Per 1,000 plus refrigerant Vaccine	Diluent	Syringes
10									
20/25									
50									

Estimated Quantities

Vial Size	Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec	Totals
10	385,000	750,000	1,035,000	810,000	2,980,000
20/25	5,310,000	7,650,000	4,720,000	8,650,000	26,330,000
50	1,750,000	150,000	250,000	—	2,150,000

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SCHEDULE OF REQUIREMENTS
VACCINES 1982

The contractor shall manufacture and supply the vaccines listed below in accordance with Articles 1 through 12 of the Schedule of Requirements at the prices and within the number of days indicated.

Vaccine: DPT

Vial Size	Price per Dose Quantity Total	1/2	1/4	Delivery Days ARO	Standard Packing Vials per Carton	Cartons per Container	Gross Weight Kgs. Per 1,000 plus refrigerant Vaccine	Diluent	Syringes
10									
20									

Estimated Quantities

Vial Size	Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec	Totals
10	6,850,000	3,260,000	2,540,000	460,000	13,110,000
20	1,980,000	1,190,000	1,740,000	1,240,000	6,150,000

Senator HAWKINS. Thank you.

Mr. UMSTEAD. As an indication of the quantities that we are buying, in round numbers, in 1982, we are buying 7 million doses of measles, 31 million doses of polio, 19 million doses of DPT, 8 million doses of tetanus toxoid, and 10 million doses of BCG.

We do ask the suppliers to bid not only on the total quantity, but also on one half quantity and one-fourth quantity so that, if appropriate, we can split the contracts.

Senator HAWKINS. Were bids solicited from U.S. firms?

Mr. UMSTEAD. Yes. We invite all qualified suppliers on the international market to bid, including U.S. suppliers. In recent years, we have invited, with respect to polio and measles, Lederle and Merck, Sharp & Dohme to bid against our tender.

Senator HAWKINS. Were bids ever awarded to them?

Mr. UMSTEAD. There was no response from Lederle against our invitation to bid. Merck, Sharp & Dohme has bid twice in the last 3 years. They were awarded the contract for measles for the period January 1979 to December 1979. That contract was extended for 6 months.

The contract called for measles vaccine in single-dose vials with syringe and needle, single-dose vials without syringe, and 10-dose vials. The quantities were 5 million doses in the single-dose vials and 4 million doses for the 10-dose vials. That was our first year under the EPI program. Our estimating procedures had not settled down yet and we did not meet those quantities, particularly in the single-dose vials.

Senator HAWKINS. Was the single-dose with syringe 41 cents per dose?

Mr. UMSTEAD. Those were 41 cents a dose; without the needle and syringe, 33 cents a dose, and in 10-dose vials 14 cents a dose.

Senator HAWKINS. And the cost per dose for 50-dose vials was 14 cents?

Mr. UMSTEAD. The 10-dose vials. Measles is not purchased in 50-dose vials.

Merck also bid the following year. Their prices were 69 cents for the single-dose with syringe, 61 cents for the single-dose, and 28.5 cents for the 10-dose. They were not awarded a contract the second year, and in 1982 Merck, Sharp & Dohme did not submit a bid.

Senator HAWKINS. I understand you often split awards among two different manufacturers and try to award the contract to manufacturers that have not been awarded the large UNICEF bid for that year, is that correct?

Mr. UMSTEAD. Yes, that is correct. Our main objective to avoid having to depend on a single supplier. The sole-source situation eliminates the incentive for competitive pricing, and would also create the risk of PAHO ending up without a supplier should production difficulties arise. So, we do try to maintain more than one supplier for each vaccine.

Additionally, there is the practical consideration that sometimes the low bidder does not have production capacity for the total quantity. A split award allows us to accept the low bid in those situations.

This is also in the best interests of the industry. The IFPMA—the International Federation of Pharmaceutical Manufacturers—

has encouraged split awards because it permits more suppliers to stay in production. In fact, in 1982 we have seven suppliers located in seven different countries.

Senator HAWKINS. Does PAHO have any quality control standards for the products you purchase?

Mr. UMSTEAD. I would refer that to Dr. Tawil.

Senator HAWKINS. Dr. Tawil, put the microphone right up close to your mouth, if you would, please.

Dr. TAWIL. Thank you, Senator Hawkins. As Mr. Cooney has mentioned this morning in his introductory statement, PAHO, in addition to being an organization of American states, is at the same time a regional office for WHO, the World Health Organization. As such, we do observe the minimum requirements which are approved by the World Health Assembly.

Senator HAWKINS. So, you have minimum requirements?

Dr. TAWIL. We have minimum requirements, which are those of the WHO. We do not have independent requirements other than those that have been recommended by the World Health Organization.

The new standards and amendments of old ones are published annually in the WHO publication, Technical Report Series, a copy of which I have in my hand. These copies are available on request to anybody. They are distributed regularly to all our offices and all producers of vaccines in Latin America.

The bacterial and viral vaccines which are supplied by the PAHO revolving fund comply strictly with all the minimum requirements recommended by WHO, of which the most important are those of safety and potency.

For the purpose of awarding a contract for the supply of a given vaccine, bidding manufacturers have to meet several different requirements, of which those related to quality are the following. They must have a license for production that is valid, and a permit as well to sell the vaccine in the country which produces it. They should submit for PAHO approval a full documentation on methods of production and testing. Samples of vaccine packaging as well as labeling and information leaflets, both in Spanish and English, must also be approved by PAHO prior to awarding a contract.

Subsequently, with each lot of vaccine supplied, the manufacturer should submit summary protocols on procedures of production and control, in addition to a certificate of release issued by the national controlling authorities in the country where the vaccine is produced.

These procedures are described in detail in the schedule of requirements to which Mr. Umstead has just referred concerning solicitation of bids. A copy will certainly be supplied by Mr. Umstead. I hope that this will answer your question, Senator.

Senator HAWKINS. Have you ever rejected a bid based on poor quality?

Dr. TAWIL. Yes, we did on several occasions. In 1981 and 1982, there have been instances where the vaccines were rejected. A vaccine was rejected at the time the manufacturer bid for the vaccine because it was proven not to meet the standards or requirements of the pertussis component. That was the DPT vaccine.

In the second instance, a contract of a manufacturer was terminated because one lot of polio vaccine supplied to one of the countries in Latin America was proven to be contaminated. We considered this a breach in consistency of the vaccine, and the manufacturer had to reestablish consistency before we resumed again the contract with him.

In the third instance, which is very recent, we have also rejected one lot of measles vaccine because it was marginal in its potency?

Senator HAWKINS. Approximately what percentage of the international firms that bid are subsidized by their own countries?

Dr. TAWIL. I think Mr. Umstead will be able to answer this question.

Mr. UMSTEAD. Senator, we do not as a matter of practice get into the costing of vaccine. Our bid analysis is done on a price basis, so we do not have a real good insight into that question. However, I think that we could say that most and perhaps all of the suppliers that we are dealing with operate in a free market economy.

I would like to just quickly read to you the names of the suppliers that we are dealing with and where they are located, and I think your committee could draw some conclusions: Connaught Laboratories in Ontario, Canada; Glaxo Group Ltd. in London, England; Hoechst in Frankfurt, West Germany; Institute of Immunology in Zagreb, Yugoslavia; Institute of Immunology and Virology, Torlak, in Belgrade, Yugoslavia; Institute Merieux in Lyon, France; Institute Pasteur in Paris, France; Instituto Sieroterapico, Sclavo, in Siena, Italy; BCG Laboratory in Tokyo, Japan; Merck, Sharp & Dohme International, Rahway, N.J.; Smith-Kline-RIT in Belgium; and Swiss Serum and Vaccine Institute in Bern, Switzerland.

Senator HAWKINS. How do the prices compare between the public and private manufacturers?

Mr. UMSTEAD. We have not noticed much variation or any particular pattern in the prices as among the various suppliers. A quick comparison here; for instance, in the 1982 bids for 10-dose polio, the prices ran 0.042, 0.039, and 0.164 among the three that bid that particular vaccine packaging. For the 20-dose, the prices ran 0.0216, 0.0750, 0.0245, 0.0330, and 0.0310. I can give you more examples, or I could just provide them for the record.

Senator HAWKINS. Those examples should suffice, thank you.

Mr. UMSTEAD. So, there is not a tremendous amount of variation; they cluster fairly close together.

Senator HAWKINS. Do any of the countries that you purchase for require by law that the children be immunized before they attend school?

Mr. UMSTEAD. I will refer that to Dr. Litvak.

Senator HAWKINS. Dr. Litvak, do any of the countries that you purchase vaccine for require by law in the country that their children be immunized before they attend school?

Dr. LITVAK. The expanded program of immunization is a PAHO program supported and approved by all the member governments of PAHO. So, it is an officially approved program by all member governments of PAHO.

In terms of local legalities in terms of acceptance to school, some of them do and some of them do not, but we do not have any interference with that part of the program.

Senator HAWKINS. There are many States in the United States that require that their children be immunized before they can enter first grade. Therefore, it is a mandated program, and I was wondering how many of the member——

Dr. LITVAK. There is a tremendous difference among the member governments there.

Senator HAWKINS. I thought so.

Aside from the large-volume purchases through the revolving fund, do you purchase smaller quantities of vaccine for member countries?

Mr. UMSTEAD. Yes, Senator. We buy a number of other vaccines, such as DT and yellow fever, rabies, rubella, and some combination vaccines—measles-rubella, for instance.

Senator HAWKINS. Are there any examples of U.S. manufacturers supplying those small contracts?

Mr. UMSTEAD. We purchase from Merck, Sharp & Dohme both the rubella and the measles-rubella. As an example, in 1981 the price for the measles-rubella in single dose vials was 93 cents a dose. For the rubella in 10-dose vials, in 1981, we paid 0.383 cents a dose, and in 1982, 41 cents a dose.

Senator HAWKINS. As individuals who have been in the business a number of years and understand its operation, how do you explain the dramatic disparities in measles prices on our chart and polio prices, domestic versus the international market? Any one of you could answer that.

Mr. UMSTEAD. Well, we are not certain that PAHO is really competent to comment on the pricing structure of the U.S. suppliers. We could, with respect to the international market, mention some factors which we believe affect the low pricing.

There is a certain amount of excess industrial capacity in the international market in the production of biologicals.

We believe that the fact that we are making a very large-volume buy with good reliable projections through one central office contributes to more efficient production and supply.

There is a very strong interest in the industry in maintaining production continuity and stability in the labor work force, even in the face of low profitability.

The IFPMA again has advised us that the industry does operate at a very low profit margin which does not provide for capital expansion or, in their view, the proper allocation of research and development costs.

Another factor, we believe, that has been expressed by the industry is that there is a certain amount of prestige attached to being a supplier to the World Health Organization.

However, the overriding factor which we believe is helping the PAHO prices low is the fact that we procure in a competitive environment.

Senator HAWKINS. So, you would say that the bottom line, the key to keeping prices low, is the competition?

Mr. UMSTEAD. Competition.

Senator HAWKINS. I want to thank you all for appearing. Is there anything you would like to add to the record? Dr. Cooney?

Dr. COONEY. Senator, we have many documents which we could supply to the committee if it is desirable.

[The document referred to follows:]

There is no distinct pattern of pricing among the various suppliers. Following are some comparisons of prices taken from the 1982 bids:

	Price per dose
Polio, 10 dose:	
RIT	0.0420
Sclavo	.0390
Hoechst	.164
Polio, 20 dose:	
Connaught	.0216
Hoechst	.0750
TorLak	.0245
RIT	.0330
Sclavo	.0310
Polio, 50 dose:	
Hoechst	.058
RIT	.030
Sclavo	.028
Measles, single dose with syringe:	
Merieux	.47
RIT	.515
Sclavo	.48
Measles, single dose:	
Merieux	.38
RIT	.42
Sclavo	.39
Measles, 10 dose:	
Merieux	.125
RIT	.145
Sclavo	.1305
Connaught	.0747

Senator HAWKINS. You are doing a wonderful job, and I really appreciate it. We might have to use you as our purchasing agents for this country since you are so efficient. You are to be commended for your efforts in helping to eradicate preventable childhood diseases and we look forward to working with you in the future. Thank you.

Dr. COONEY. Thank you.

Mr. UMSTEAD. Thank you.

Senator HAWKINS. You are excused at this time.

Our second panel of witnesses includes Dr. Lewis Sarett, who is the senior vice president, science and technology, at Merck, Sharp & Dohme. Dr. Sarett is accompanied by Mr. Richard Morr, director of marketing and planning for vaccines.

Also on this panel we have Mr. Jack Bowman, president of Lederle Laboratories. He is accompanied by Dr. Francis Cano.

Welcome, gentlemen. We thank you for appearing before this subcommittee today.

Dr. Sarett, could you please summarize your role in the production of vaccines, with specific focus on your involvement with the MMR formula?

STATEMENT OF LEWIS H. SARETT, SENIOR VICE PRESIDENT, SCIENCE AND TECHNOLOGY, MERCK & CO., INC., RAHWAY, N.J., ACCOMPANIED BY RICHARD D. MORR, DIRECTOR OF MARKETING AND PLANNING FOR VACCINES, MERCK & CO.; AND JACK BOWMAN, PRESIDENT, LEDERLE LABORATORIES, AMERICAN CYANAMID, WAYNE, N.J., ACCOMPANIED BY FRANCIS R. CANO, LEDERLE VACCINE PRODUCTION, LEDERLE LABORATORIES, AMERICAN CYANAMID, A PANEL

Dr. SARETT. Senator, I am pleased to be here to help this subcommittee understand and deal with the questions before it. I might say that I feel a very strong personal identification with this issue because Merck's long and continued commitment in the field of immunization and vaccines has been based upon an energetic and highly productive research program which is dependent upon adequate revenues from the sales of our products.

Our involvement with vaccines over the past quarter century has been marked by considerable progress. I noted the comments of Dr. Krause of the National Institute of Allergy and Infectious Diseases. He was quoted in the New York Times a couple of days ago. He pointed out that the 14 vaccines effective against infectious agents amount to a little more than 1 vaccine per decade since the time of Louis Pasteur. In fact, much of that progress has been in recent decades and our laboratories have been privileged to play a pivotal role in most of these advances.

The current era started with our introduction of a live virus measles vaccine in 1963, followed by the mumps vaccine in 1968, the rubella vaccine in 1969, the triple vaccine in 1971, the pneumococcal pneumonia vaccine in 1978, and our introduction this summer of the first hepatitis B vaccine in this country. Many brilliant scientists have contributed to this progress along the way, and we are proud of the contributions made by Merck.

Perhaps even more exciting is the fact that aggressive work is underway in many other diseases. We are making progress with a vaccine against hepatitis A, and are continuing intensive work with herpes simplex 2, a disease which is of epidemic proportions in this country; with gonorrhea; and with cytomegalovirus, which inflicts fetal damage and is a major cause of congenital mental retardation.

Funding this work is a demanding task, given the nature of this market. Because vaccines often provide a lasting immunity and are designed to eradicate the disease in question, they eradicate the market at the same time.

Our answer, of course, has been to press forward continually for the next vaccine against another unsolved disease problem. Our estimates indicate that we are spending an unusually high amount on research and development—perhaps as high as 25 percent of our sales.

The key factor in our company's handling of its products is the need and obligation we feel to maintain our sales income at a level that will support our major research commitment. We believe that the results have been enormously cost effective in public health terms. We believe our prices are very fair for the value received, unmatched by almost any other product we can think of.

Many factors of business judgment go into each pricing decision. Three key factors appear to have been particularly significant in our decisions on MMR in the past several years: first, the impact of inflation on our total business; second, the declining volume of purchases; third, our very conscious commitment to maintain our very productive research organization in the face of a discouraging market for these products.

Regarding inflation, first, we find that over the past 10 years, our vaccine pricing failed to keep pace with the inflationary costs that impacted our total operations. Overall, Merck, Sharp & Dohme prices have significantly lagged the gross national product deflator and the Consumer Price Index, as you will see later from exhibits which Mr. Morr has with him.

Regarding volume of purchase, we find that after the major initial thrust in 1976, the overall unit sales of our pediatric vaccines to CDC have declined by over 50 percent since 1976. Circumstances have continually changed, necessitating, of course, a change in the terms that we offered.

I have already described to you how fundamental our research program is in our whole involvement in the vaccine business. I just want to list two other considerations.

First, persons not involved in our business might understandably ask about the specific cost elements that impact the price of a particular product. In fact, our particular business is a high-technology business, not a commodity business, and it does not run on a cost-plus basis.

Rather, in facing pricing decisions, we assess our total business situation, looking at the cost elements affecting our total business, including research and development, provision for capital needs, potential volume, and many other considerations.

Second, one by one, U.S. vaccine manufacturers have decided that this business is not commercially attractive and have dropped out. However, we believe and we hope it can be economically sound if there is sufficient demand for vaccines, if we can have adequate pricing, and if we can thereby support the research program needed to develop new vaccines.

Third, a major vulnerability is the unresolved public policy problem of liability for unavoidable injury in mass immunization programs. This is clearly a major impediment to commercial initiative in the vaccine field, and we hope that Congress will be willing to deal directly with it.

In summary, Senator, Merck's commitment to a productive research program underlies our entire handling of our vaccine business. Key influences in our recent pricing actions also include the effort to cope with the impact of inflation on our total business, and reflect the declining volume of vaccine sold.

Pricing actions occur not on the basis of a series of costs adding up to a total price, but rather on the basis of business judgment on these products and on our entire business. We try very hard, as a matter of sound business, to be fair and consistent in our pricing. We believe that the result of our research and our business actions is a product that delivers more than reasonable value for its cost.

Thank you. Now, knowing that you are interested in more specific details of our measles-mumps-rubella, I will call on Mr. Morr to provide you with some more detailed information.

Senator HAWKINS. First, I would like to establish that you are the sole source for MMR in the United States today. Is that correct?

Dr. SARETT. That is correct.

Senator HAWKINS. Mr. Morr, you may proceed.

Mr. MORR. I would prefer to walk over to the charts.

Senator HAWKINS. Please speak loudly so they can hear you all over the room. The court reporter must hear you, also.

Mr. MORR. As Dr. Sarett mentioned, there are many factors of business judgment that go into our establishment of prices at Merck, Sharp & Dohme, and the three key factors that he mentioned that I will reiterate are, No. 1, the serious impact that inflation has had on our business in general; second, the fact that volume declines have been significant in recent years; and third, this very conscious commitment to a productive program in this field of vaccines.

The first chart that I would like to refer you to goes back over the past decade, starting with the year 1972, and, of course, all these indices are put in at 100. The top line on this graph is the Consumer Price Index, and it is, as you know, a broad-based Government index. It is made up of a market basket of products, services, and various homeowner costs. That has more than doubled in the last decade.

The second line on this graph and one that closely parallels the Consumer Price Index is the gross national product deflator. That particular index, probably, of all these indexes, is the broadest in base and most truly represents the U.S. economy.

The third line is a prescription drug index; it is known as the Firestone index. Again, over this same time period, it follows somewhat the same pattern, but certainly those prices have lagged behind the general economic indexes.

Now, the last two lines in this chart take a look more specifically at measles-mumps-rubella, known as the triple combination vaccine MMR. The top of these two lines shows the pattern of price increases in the private sector over that same period of 10 years, and the bottom line represents the Federal Government program.

Now, I should explain the bottom line, because in the years 1972 through 1975, that line more closely parallels what was going on in the private sector because it is based on our Federal supply schedule. During that period of time, the CDC did not choose to buy MMR, the triple component vaccine, but was buying separate, single and one-component vaccines.

Senator HAWKINS. The States were buying MMR combined individually?

Mr. MORR. The States were buying primarily individually—yes.

Senator HAWKINS. From 1972 to 1975?

Mr. MORR. In the next chart, I will get into the differentials between the State pricing, Federal pricing, and so forth.

Beginning in the year 1976, based on the infusion of additional significant Federal funding to fund the national immunization initiative program to eliminate many of these childhood diseases, the

CDC for the first time on this particular product, MMR, entered into a contract with Merck. We arrived at a price and, as you see, it dropped down significantly.

This price was arrived at based on several factors. One was the fact that they expected their estimated volume of purchases to increase dramatically. The second is that they agreed to make their purchase on a nonreturnable basis, because the return of unused vaccine not only tends to be wasteful, but it represents a relatively high percentage of our overall sales.

The third factor was, as I mentioned before, this infusion of additional Federal funding. So, based on that, we, together with highly professional and highly qualified purchasing people at the Centers for Disease Control, entered into what we both considered to be a very fair price for MMR.

As you can see, since 1975, those prices have trended upward, and I will focus just briefly——

Senator HAWKINS. At any point in that line that you are pointing to, were there other producers of this vaccine? How about from 1975 to 1978?

Mr. MORR. We have not had any competition on MMR, the triple-component vaccine. Prior to this time period, however, there was competition on the single-component vaccines—measles and rubella, as examples.

Now, let me focus on the past 2 years because I know that is probably of primary interest to your committee. Over the period of the last three CDC contracts, which is a span of time over the last 18 months, our prices have increased significantly.

If I back up in time from the most recent back to 1980, we increased the price 12 percent on MMR in May 1982 to CDC. Prior to that, we made an increase in October of 28.8 percent. Now, that reflected two prices changes that had taken place in the private sector and probably can best be explained by going to the second chart.

In the private sector, back in 1981, we had an increase in price in April of 12 percent, followed by a subsequent price increase in September of 15 percent, followed again in May 1982 by an additional 12 percent. Now, the combination of those things with regard to CDC contracts—the CDC was protected from any particular price increase over a 12-month period of time.

More recently, beginning in October 1981, the CDC, at that point very uncertain about the level of Federal funding for the childhood immunization programs, requested and agreed that we would set up a 6-month contract for the first time. During that period of time, they were protected from any additional price increases based on the uncertainty of the level of Federal funding.

Senator HAWKINS. What was that price per dose at that time?

Mr. MORR. The price per dose to the CDC today, which became effective May 1, 1982, is $4.50 per dose to cover all three childhood diseases. The price that became effective October 1, 1981, was $4.02 a dose. If we go back to the base period, which was the contract that went into effect 12 months prior to that, it was $3.12 a dose.

Senator HAWKINS. So, it was $3.12 in 1980, $4.02——

Mr. MORR. The price has gone from $3.12 a dose in October 1980 to $4.50 per dose currently.

Senator HAWKINS. Do you have any idea what it is going to be in 1983?

Mr. MORR. Pardon me?

Senator HAWKINS. Do you know what your next contract price will be?

Mr. MORR. Do we have any idea?

Senator HAWKINS. On the next price increase.

Mr. MORR. I think at this stage of the game, we do not have any idea what that will be. I think a lot of it will be, as I mentioned earlier, the many factors that make up our business judgment about pricing. Some of them have to do with the serious effect of inflation on our costs.

Senator HAWKINS. Inflation has gone down, as I understand it.

Mr. MORR. Right. The next CDC contract comes up for renewal at the end of calendar year 1982, and at that point in time, we will have to make a judgment based on volume of purchases and based on economic factors, such as the effect of inflation on our business in general.

Senator HAWKINS. While you are looking on that chart, does the green line represent the city/county/State prices?

Mr. MORR. Yes.

Senator HAWKINS. What are the prices you charge those?

Mr. MORR. City/county/State prices, depending on the volume purchased—by the way, I should mention here that all our pricing is consistent from one State to the other, based on the volume purchased.

For example, I selected out the most usual volume of purchase by a State in a 25,000- to 50,000-dose range for MMR. In 1982, our current price is $7.66 a dose. That price does go down based on higher volumes. In 1981, the price was $6.84. Prior to that, it was $5.31.

So, the comparison would be a CDC price of $4.50 and a city/county/State price of $7.66, depending on volume. It can be lower than that; that, I would say, is the average, compared with a private sector price of $10.44.

Senator HAWKINS. What would it be to a physician?

Mr. MORR. These are the physician prices in the top line.

Essentially, what we are saying is that our pricing increase patterns have remained consistent over time, although the level of actual prices has been lower depending on the volume purchased. So, the private physician, military, and local government installations could certainly purchase this vaccine and the price increases would have maintained the same pattern over that 10-year period, with the exception, of course, of the CDC, who all of a sudden purchased much larger volumes.

This leads me into the third slide to give you some feel for what has happened in the volume purchased by the Government. Now, these include not only CDC purchases, but State and Federal purchases; they have been lumped together.

The top line shows you the volume change in terms of antigens, and I wanted to explain that. If one purchases one dose of MMR, that contains three antigens, being measles, mumps, and rubella. So, we have both of those factors laid out in the chart.

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SCHEDULE OF REQUIREMENTS
VACCINES 1982

The contractor shall manufacture and supply the vaccines listed below in accordance with Articles 1 through 12 of the Schedule of Requirements at the prices and within the number of days indicated.

Vaccine: BCG

Vial Size	Price per Dose Quantity Total	1/2	1/4	Delivery Days ARO	Standard Packing Vials per Carton	Cartons per Container	Gross Weight Kgs. Per 1,000 plus refrigerant Vaccine	Diluent	Syringes
10									
20									
50									

Estimated Quantities

Vial Size	Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec	Totals
10	155,000	150,000	150,000	150,000	605,000
20	3,430,000	1,740,000	1,765,000	1,840,000	8,775,000
50	110,000	500,000	200,000	100,000	910,000

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SCHEDULE OF REQUIREMENTS
VACCINES 1982

The contractor shall manufacture and supply the vaccines listed below in accordance with Articles 1 through 12 of the Schedule of Requirements at the prices and within the number of days indicated.

Vaccine: TT

Vial Size	Price per Dose Quantity Total	1/2	1/4	Delivery Days A/O	Standard Packing Vials per Carton	Cartons per Container	Gross Weight Kgs. Per 1,000 plus refrigerant Vaccine	Diluent	Syringes
10									
20									

Estimated Quantities

Vial Size	Jan-Mar	Apr-Jun	Jul-Sep	Oct-Dec	Totals
10	2,110,000	1,950,000	1,000,000	1,050,000	6,110,000
20	850,000	400,000	830,000	400,000	2,480,000

The top is in terms of antigens and the bottom is in terms of doses, but the curves for both have remained relatively the same. Again, if you go back to the year 1976, with the infusion of additional Federal funding, volume increased dramatically. They stayed approximately the same. In terms of antigens, it dropped off a little bit, and in terms of doses because of the move toward MMR for the next 2 years, during which time the CDC received, again, the additional infusion of Federal funding.

Since 1978 through to the current year, volume has dramatically fallen off. It has fallen to about 50 percent of the level in terms of antigens, and more than that; it is almost a 78-percent decline from the base year of 1976–77.

Therefore, some of the reasons that we have felt obligated to take increases in a rather significant way in the past 2 years have had an awful lot to do with the volume declines which you see depicted on these charts, the serious impact of inflation that has taken place over a long period of time, not to mention what Dr. Sarett referred to earlier, which has actually been a 20-percent increase in the research and development budgets and spending level that have been estimated over this same time period.

We have invested capital expenditures in the vaccine area in particular, and they have run over $50 million in the past 2 years. We find it difficult to maintain our position in this market in that long-lasting immunity does cause the market to dry up considerably.

I think, on balance, we feel that we have actually shown great restraint in not increasing prices more than we have. Part of that is based on the sense of responsibility that in public health programs, children really should be able to be vaccinated against these childhood diseases.

In summary, MMR seems to be a relatively good bargain when one considers that a child can be protected against three childhood diseases for a lifetime for $4.50 when receiving MMR purchases through the CDC.

Are there any other questions?

Senator HAWKINS. Thank you. I have some other questions for you, but that will be fine at this time.

I would like to turn to Lederle at this time. Mr. Bowman, would you please describe Lederle's involvement in the development of polio vaccine?

Mr. BOWMAN. Lederle started the vaccine——

Senator HAWKINS. Put the microphone right up to your mouth please.

Mr. BOWMAN. OK. Lederle started in vaccines a very long time ago in 1906, with Dr. Lederle establishing the first manufacturing site for a purified diptheria vaccine in the United States. And though we are probably better known as suppliers of antibiotics, cancer medicine and arthritis medicine, we remain committed to providing vaccines for the U.S. population.

As the committee knows, we are one of the few companies remaining in the United States that has chosen to continue manufacturing vaccines.

We are tremendously proud of our past and present research accomplishments. We are equally proud of the fact that we can still

offer a vaccine against polio that gives lifetime immunity for about $1.50, if it is bought through the CDC, or for about $5 for the required three doses if bought through the private sector.

We are very proud, also, of our ability to provide protection against diptheria, pertussis, and tetanus for only about $1.82 for the required four doses. To put that into perspective, the cost for a youngster for 1 hour's play on one of the new coin-operated video games can be higher than Lederle's average price for vaccines that provide lifelong protection against all four of these diseases.

Inflation in the past couple of decades has seriously challenged our ability to keep our prices at a reasonable level. Since the introduction of oral polio vaccine, which was 19 years ago, the average selling price for Orimune has increased 145 percent. The average medical care cost during that same period increased 244 percent. So, we were able to stay under the rate of growth for medical care as a whole.

In the same period of time—actually, in 20 years—the price increase on Lederle's DPT has been 159 percent, against a medical care cost increase of 252 percent.

During the past decade, two of the three manufacturers of oral polio vaccine have chosen to leave the U.S. market, and of the seven companies that are licensed to manufacture DPT in the United States, only three continue to do so. Lederle has chosen to stay in both as a supplier of both vaccines.

We have spent tens of millions of dollars on research in vaccines over the last decades. We were pioneers in polio vaccine, and our research there required about 16 years to bring to fruition. We continue to have active programs in development of vaccines for such presently threatening diseases as haemophilus influenzae. This project, which has been identified as a high-priority project by the National Institutes of Health, will probably cost us about $50 million, and we will have to carry out clinical trials on something like 30,000 infants in order to statistically prove the effectiveness of the vaccine.

But we are willing to make that commitment, and to stay in the vaccine business and to fund that business out of the earnings from the existing products. We have also begun work on an improved pertussis vaccine. As Dr. Sarett mentioned, Merck is working, on a vaccine for herpes type 2; Lederle is also very actively engaged in such an effort.

It is our expectation that we will be able to bring these efforts to a successful conclusion, inasmuch as effective immunizing agents not only save lives and prevent illness, but they can be a significant force in reducing the Nation's growing bill for medical care.

Senator HAWKINS. What is your return policy for unused vaccines?

Mr. BOWMAN. Our return policy is, for the CDC, that they purchase with the understanding that they cannot return.

Senator HAWKINS. What about the States?

Mr. BOWMAN. States, in many cases, have the ability to return outdated merchandise for surplus merchandise.

Senator HAWKINS. What do you mean, "in many instances?" Some States can and some States cannot?

Mr. BOWMAN. If they wanted to try to achieve a lower bid price by saying this is sold on a nonreturnable basis, we would take that into consi[illegible]tion. Returns can be fairly significant.

[The prepared statement of Mr. Bowman follows:]

CYANAMID

Information from Lederle

Statement by Mr. Jack Bowman, President
Lederle Laboratories, Division of American
Cyanamid Company

Prepared for Submission to
the Subcommittee on Investigations and General
Oversight of the Senate Committee on Labor and
Human Resources

Washington, D.C.

July 22, 1982

With the Chairman's permission I would like to submit for the record the following information concerning Lederle Laboratories and vaccines.

Lederle Laboratories has been a pioneer in the development and production of vaccines since 1906. Dr. Ernst Lederle had served in several New York City reform administrations at the turn of the century as Commissioner of Health. The lack of a United States source of purified diphtheria vaccine during his tenure resulted in his establishment of the company for the sole purpose of manufacturing superior vaccines. Lederle became a division of American Cyanamid Company in 1930. The resulting influx of new investment capital permitted a major research and development effort in the anti-infective and pharmaceutical fields resulting in a number of noteworthy breakthroughs in the cure or management of serious diseases.

Lederle's dedication to preventive medicine has continued to this day. As the Committee knows, we are one of the few U.S. companies left who have chosen to continue to manufacture vaccines.

We are extremely proud of our past and present research accomplishments. We are equally proud of the fact that we can still offer a vaccine against poliomyelitis which confers lifetime immunity for an average selling price of about $5 for the required three doses. And, even more remarkable in today's inflationary climate, our average selling price for a vaccine which confers lifetime immunity against diphtheria, pertussis and tetanus, is about $1.82 for the required 4 doses. The cost to a youngster for an hour's play on one of the new coin-operated video games can be higher than Lederle Laboratories' average price for vaccines which provide life-long immunization against four child killer diseases.

In the face of almost two decades of unprecedented inflation and rising costs, Lederle has successfully endeavored to keep price increases for its vaccines to the minimum necessary to maintain a viable vaccine business. Since the introduction of Lederle's oral polio vaccine in 1963, our average selling price for ORIMUNE® increased 145% against a medical care cost increase during the same 19-year period of 244%. For the 20-year period 1962-82, the price increase of Lederle's DPT Vaccine (TRI-IMMUNOL®) was held to 159% against a medical care cost increase of 252% during the same period.

During the past decade two of the three oral polio manufacturers chose to leave the market and while seven manufacturers hold U.S. licenses for the manufacture of DPT, only three presently remain in that market. The total size of the U.S. DPT market in 1982 is $6.3 million. Lederle's sales account for a minor part of that market.

That rising costs and inadequate prices have been a significant factor in the decisions to withdraw from vaccine markets is attested to by the conclusions of a government study, Reports and Recommendations of the National Immunization Work Groups. This study, initiated by the Office of the U.S. Assistant Secretary for Health, and published March 15, 1977, stated:

> "While the potential capability of American industry to supply vaccine requirements is unarguable, there has been a steady attrition of specific pharmaceutical manufacturers from the entire field of biologics, as shown in Table 1 (attached). A relatively low profit margin, high production risks, increasing costs of research and development, difficulties in clinical testing, and increasingly stringent governmental standards of safety and efficacy are all formidable constraints to private investment." (page 1)

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Since its founding as a vaccine manufacturer more than three-quarters of a century ago, Lederle has invested many tens of millions of dollars in vaccine research and development. Its pioneering research for an oral polio vaccine extended over 16 years. Despite the problems which have beset the vaccine business sector over the past years, Lederle's continued dedication to the field of preventive medicine is attested to by its very active research program to develop vaccines for serious diseases for which immunizing agents are not now available.

These programs are in various stages of development ranging from basic research to the last phases of clinical trials. An example of a research project that recently resulted in a new product is the nine-year-long development of the pneumococcal polysaccharide vaccine, PNU-IMUNE®. Pneumococcal pneumonia is the main cause of mortality that follows influenza epidemics. PNU-IMUNE is a broad-spectrum vaccine effective against 14 capsular types accounting for at least 80% of all pneumococcal disease in the U.S.

Some other Lederle R & D programs to develop new vaccines include development of a haemophilus influenzae vaccine, which is currently in active clinical trials. The project has been identified as a high priority project by the National Institutes of Health. It is estimated that it will take at least 50 million dollars to develop the H-influenzae vaccine, and it will involve extensive efficacy studies in approximately 30,000 infants.

Successful development of this vaccine can prevent haemophilus influenzae which is the main cause of acute bacterial meningitis. This infection results in the death of about 10 percent of those affected, many of them young children. Nearly half of the survivors suffer long-term disability, including brain damage.

In addition, Lederle is working on development of an a-cellular pertussis vaccine, and has most recently begun a research program for a herpes virus vaccine which is expected to cost at least $30 million.

It is Lederle's expectation and hope that we will be able to bring these efforts to a successful conclusion inasmuch as effective immunizing agents not only save lives and prevent illness, but can be a significant force in reducing this nation's growing bill for medical care.

PS:7/82

Senator HAWKINS. Dr. Sarett, what is Merck, Sharp, and Dohme's return policy?

Dr. SARETT. Mr. Morr would you like to address that?

Mr. MORR. Yes. Our return policy is much the same as that described by Lederle, and that is that for the CDC, the contract agreements are that they cannot purchase on a returnable basis.

Senator HAWKINS. They cannot?

Mr. MORR. They cannot.

Senator HAWKINS. What about the States?

Mr. MORR. With regard to States, up until May of 1982, we permitted States to return unused vaccine. We changed that policy, beginning in May, to a nonreturnable policy for the States, and let me, if you will, give you a couple of reasons for that.

First of all, what we found was happening was a minority of States were tending to get the best price by overestimating the amount of doses they would use. They would simply buy much larger quantities than the need existed for, and simply then return unused vaccine, which was not only wasteful but tended to raise the price across the board to other people in the long run.

So, what we are doing this year for the first time is experimenting with selling it to States on a nonreturnable basis.

Senator HAWKINS. I am going to run and vote. I have a lot more questions for you, if you will excuse me.

[Whereupon, a brief recess was taken.]

Senator HAWKINS. We will resume. Can I have order, please?

Dr. Sarett, do you make a profit on MMR?

Dr. SARETT. It is very difficult to allocate profitability to any single product. The way that our business operates, we do our pricing on the basis of very many factors, and so with any particular product, it is not just a question of adding up prices of the raw materials, the price of labor, and so on. It is more complicated than that.

Senator HAWKINS. Do you lose money on it?

Dr. SARETT. In some circumstances, I expect that we do. If you would like me to elaborate on that, I will be glad to. Our overseas business is composed of two segments. One of them is the private sector, where our prices are quite consistent with our domestic prices.

In the bid business overseas, that is rather a different situation. We have bid in the past, as you heard from PAHO, and we have offered vaccine, including MMR, at lower prices. Now, those lower prices historically are conditioned partly on the fact that we would like to cooperate in providing less developed countries such as PAHO serves with vaccines at the best price that we can produce for them.

Many Members of Congress have reminded us, and we have reminded ourselves in the pharmaceutical industry, that we have a responsibility for helping out those nations in which these viral diseases are even more serious and more fatal in many cases than in the United States. So, as a general policy, we have tried to cooperate.

Now, in many of these instances, therefore, we have put in low bids. Also for the reasons that were mentioned by the experts from PAHO, we have tried to put in low bids. These included continuity

of production to avoid unemployment, continued use of our facilities, and factors of that nature.

Now, history shows, however, that, in general, a research-intensive company such as Merck is not very successful at bidding competitively overseas. And, in general, as PAHO's testimony again indicated, although in 1979 we were a successful bidder, I think, for a measles vaccine, in 1980 we were unsuccessful; in 1981, we did not put in a bid at all.

So, as we look now into the future, I believe that we can see all too clearly that the economics of bid business overseas is discouraging for us. We hope to be able to continue, perhaps, on a public service basis.

Senator HAWKINS. Mr. Bowman, do you make a profit on polio vaccine?

Mr. BOWMAN. Yes, we do. I think we have now finally reached the point where oral polio vaccine is standing on its own feet, supporting itself and returning a modest profit to us, which has not been the case in the past.

Senator HAWKINS. Could you give us that margin?

Mr. BOWMAN. I cannot, for a couple of reasons. First, as Dr. Sarett has pointed out, it is extremely difficult to put a precise profit margin on a product because of difficulty in allocating research and other costs.

Second, quite frankly, product profit information is proprietary information which I do not want to share with Dr. Sarett. [Laughter.]

Senator HAWKINS. Well, there is no competition, so do not worry about it. [Laughter.]

Senator HAWKINS. Dr. Sarett, has competition, or potential competition, ever been a factor in the MMR domestic market?

Dr. SARETT. We have been in the position of being the sole supplier of MMR.

Senator HAWKINS. What about the years 1975 to 1978?

Dr. SARETT. During that period, yes.

Senator HAWKINS. The prices remained consistently around $2.40 during that period of time. According to the Bureau of Biologics of the Food and Drug Administration, Dow Chemical Co. was awarded a license to market MMR vaccine in April of 1974. Is that correct?

[Information supplied follows:]

(712)	03-04-70		Poison Ivy Extract

LICENSE NUMBER	ESTABLISHMENT
103	ALLERGY LABORATORIES, INC. Mr. Patrick K. Smith Plaza Court Bldg., Suite 204, 1100 Classen Dr. Oklahoma City, OK 73103

	DATE OF LICENSE	DATE OF REVOCATION	PRODUCTS
	11-01-78		Establishment License
(701)	04-10-41		Allergenic Extracts

LICENSE NUMBER	ESTABLISHMENT
110	DOW CHEMICAL COMPANY (THE) S. J. Cieciura, Ph.D. P.O. Box 68511 Indianapolis, IN 46268

	DATE OF LICENSE	DATE OF REVOCATION	PRODUCTS
	10-01-32	06-21-78	Establishment License
(905)	09-11-70	06-07-77	Diphtheria & Tetanus Toxoids & Pertussis Vaccine Adsorbed
(903)	09-11-70	06-07-77	Diphtheria & Tetanus Toxoids Adsorbed
(201)	09-18-34	06-07-77	Diphtheria Toxoid
(908)	09-11-70	06-07-77	Diphtheria Toxoid and Pertussis Vaccine Adsorbed
(414)	10-14-48	06-07-77	Immune Serum Globulin (Human)
(305)	04-17-74	06-21-78	Measles and Rubella Virus Vaccine, Live
(303)	02-05-65	06-21-78	Measles Virus Vaccine, Live, Attenuated
(304)	04-17-74	06-21-78	Measles, Mumps and Rubella Virus Vaccine, Live
(308)	04-17-74	06-21-78	Mumps Virus Vaccine, Live
(422)	02-06-67	06-07-77	Normal Serum Albumin (Human)
(834)	10-01-32	06-07-77	Pertussis Vaccine
(431)	11-02-71	06-21-78	Rho (D) Immune Globulin (Human)

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LICENSE NUMBER	ESTABLISHMENT
110	DOW CHEMICAL COMPANY (THE) (Continued)

	DATE OF LICENSE	DATE OF REVOCATION	PRODUCTS
(318)	03-01-74	06-21-78	Rubella Virus Vaccine, Live
(433)	05-20-68	06-07-77	Tetanus Immune Globulin (Human)
(205)	08-01-36	06-07-77	Tetanus Toxoid
(206)	09-01-70	06-07-77	Tetanus Toxoid Adsorbed

LICENSE NUMBER	ESTABLISHMENT
113	MICHAEL REESE RESEARCH FOUNDATION Armando R. Orlina, M.D. 530 E. 31st Street Chicago, IL 60616

	DATE OF LICENSE	DATE OF REVOCATION	PRODUCTS
	07-07-34		Establishment License
(429)	02-10-71		Red Blood Cells (Human)
(432)	08-10-64		Single Donor Plasma (Human)
(436)	04-10-68		Whole Blood (Human) ACD
(437)	06-17-69		Whole Blood (Human) CPD
(438)	04-10-68		Whole Blood (Human) Heparin
	11-2 82		Platelet Concentrate (Pheresis)

LICENSE NUMBER	ESTABLISHMENT
119	BARRY LABORATORIES, INC. Mr. Steven Zudeck 461 N.E. 27th Street Pompano Beach, FL 33064

Dr. SARETT. Yes.

Senator HAWKINS. That license was revoked in 1978.

Are you telling us that at no time during those 4 years did the presence of another licensed manufacturer have an impact on your prices?

Dr. SARETT. I think the lesson that is to be learned from the fact that they were licensed by us to manufacture MMR and they chose not to do it is a clear indication of the lack of profitability of MMR.

Senator HAWKINS. At that time?

Dr. SARETT. At that time.

Senator HAWKINS. And when they decided not to manufacture, then your price went up?

Dr. SARETT. Our price went up for the reasons that Mr. Morr mentioned, because of volume changes, because of inflation and other factors.

Senator HAWKINS. We show the affect of competition on chart V. Your price stayed low as long as Dow had a license; and when it was revoked, the price went up.

[Chart V follows:]

Mr. MORR. Let me explain that. Those prices, as I tried to mention earlier, had more to do with the fact that there was, all of a sudden, a mass infusion of additional Federal funding and the volume of purchases went up dramatically.

I think we would be foolish to sit here and say that the threat of competition or future competition did not have some bearing. I think, as we mentioned earlier, there are many factors of business judgment that go into a lot of our decisions based on pricing. Competition is one of those factors. The threat of future competition is certainly one of those factors.

Senator HAWKINS. Mr. Bowman, has competition or the threat of competition ever been a factor in the polio domestic market?

Mr. BOWMAN. There were competitors until 1975. Wyeth dropped out in 1973, Pfizer in 1975. Since then, we have been the sole supplier in the United States.

Senator HAWKINS. For the DPT market, does the presence of competition explain why prices have stayed relatively stable over the years?

Mr. BOWMAN. They really have not. If you look at them over 20 years, the average selling price of DPT in the United States has increased exactly as much as oral polio—a 159 percent increase.

Senator HAWKINS. How about the last 5 years?

Mr. BOWMAN. The last 5 years have been messed up by production problems.

Senator HAWKINS. Is that a scientific term? [Laughter.]

Mr. BOWMAN. That is what Dr. Cano told me, yes.

Senator HAWKINS. We understand that. [Laughter.]

Mr. BOWMAN. Our prices were accelerated in 1979 due to the fact that we ran into a production problem which made it necessary for us to buy vaccines from other suppliers ourselves to resell, and this perturbed the pattern over that time. After we were able to get back into business ourselves, we sold at rather low prices just to get back the business we had lost.

Senator HAWKINS. Dr. Sarett, what is the attitude of the company about being the sole-source provider for MMR?

Dr. SARETT. We are very proud that our research has culminated in novel technology which confers a limited monopoly on us through the patent system.

Senator HAWKINS. Are you proud of this even though you may not be making any money on it?

Dr. SARETT. Whether or not we make money, it provides an opportunity for making the product available under favorable conditions to us. It acts as a reward for past research contributions; it acts as an incentive for future ones.

Of course, in addition to our exclusive position in the United States for the moment—and I say "for the moment" because these things never last terribly long—there are other competitors who are very skillful and who have introduced overseas some measles-mumps-rubella, and perhaps it will not be too long before it is introduced in the United States and we will have price competition on the same product, or a very similar product.

But there are other kinds of competition. There is competition for service to your client, competition for reliability of delivery, competition in packaging, competition in research.

Moreover, the customers whom we have for the vaccine are the same customers or similar customers to the ones we have for our pharmaceutical products, and there is no way, in a practical world, that we can exploit our monopoly position, if you will, by overcharging for a vaccine because we know that retribution will be a hundredfold worse in terms of loss of respect and loss of purchasing for our pharmaceutical products, and we sell a great deal more of those than we do of the vaccines.

So, therefore, all of these things are constraints for us that make what might otherwise be a monopoly position into one in which there is very truly competition.

Senator HAWKINS. Mr. Bowman, what is Lederle's assessment of its role as a sole-source provider for polio?

Mr. BOWMAN. We take that role very seriously. We are pleased that, although our competitors did have to get out of the market because it was simply not a very good business to be in, we found a way to stay in. We know that it is absolutely vital that someone—a domestic source—be ready to supply the U.S. population with oral polio vaccine, and we are proud that we are able to do that.

There are about seven or eight cases of polio a year in the United States now; there were 52,000 a year before polio vaccine. And we intend to stay in this business and provide the vaccine for the population.

Senator HAWKINS. Besides, it is financially beneficial?

Mr. BOWMAN. Well, it is helping us to be able to work now on a herpes vaccine and on a haemophilus influenzae vaccine, and I think that that promises so much for the population that it is very exciting.

Senator HAWKINS. Does it bother you that Merck is also working with herpes?

Mr. BOWMAN. It depends on how far along they are. [Laughter.]

Senator HAWKINS. Dr. Sarett, representatives from the Pan American Health Organization testified earlier today that Merck was awarded a contract for measles vaccine at a bid of 41 cents per dose in 1979. They also testified that the measles products sold in 1979 and 1980 came in lots of 10, with syringes, from your plant in Rahway, N.J. We have a copy of the contract; I am sure you are also aware of it.

How can you justify charging nearly three times as much to the U.S. Government as you did to foreign countries, and then the next year again submitting a bid also substantially below Federal U.S. prices?

[Information supplied for the record follows:]

ORGANIZACION PANAMERICANA DE LA SALUD
Oficina Sanitaria Panamericana, Oficina Regional de la
ORGANIZACION MUNDIAL DE LA SALUD

525 TWENTY-THIRD STREET, N.W., WASHINGTON, D. C. 20037, E.U.A. CABLEGRAMAS: OFSANPAN

REFERENCIA: TELEFONO 223-4700

APO-EPI-5

13 January 1979

Merck, Sharp & Dohme, Inc.
P.O. Box 2000
Rahway, New Jersey 07065

Attn: Mr. E. C. O'Hara

Dear Mr. O'Hara:

Attached herewith is a signed copy of the contract between your company and the Pan American Health Organization for the supply of vaccines in 1979. This contract confirms and formalizes our telegram notification to you in December 1978. Please execute one copy of the contract on behalf of your company and return it to this office for our records.

Thank you for your cooperation.

Very truly yours,

Walter W. Umstead
Contracting Officer

Best Available Copy

RECEIVED
SUPPLY OFFICE
PAHO/WHO

PAN AMERICAN HEALTH ORGANIZATION
525 Twenty-third Street, N.W.
Washington, D.C. 20037

'79 JAN 30 PM 4:18

Contract PAHO-EPI-5-79

The Pan American Health Organization ("PAHO"), represented by the Contracting Officer executing this contract, and Merck Sharp & Dohme International, Rahway, N.J. ("Contractor"), agree that the contractor will supply vaccines as described herein to PAHO Member Countries, as and when ordered by PAHO, during a one year period from 1 January 1979 to 31 December 1979, in accordance with the terms and conditions of PAHO INVITATION FOR BIDS, VACCINE SUPPLY CONTRACTS, APO-EPI-1979 attached at ANNEX I, and the following: (1) Contractor's bid dated 20 November 1978, (2) General Conditions and Instructions, attached at ANNEX II, (3) Sections A through E set forth herein.

Section A - Confirmation of Telegraphic Notice of Contract

This contract confirms PAHO telex APO-EPI-80005 3698, dated 7 December 1978, which accepted Contractor's bid dated 20 November 1978 for the vaccines listed in Section B - Schedule of Supplies.

Section B - Schedule of Supplies

Item No	Description	Doses per vial	Price per dose
1	Measles Vaccine, live, Attenuated (ATTENUVAX) freeze dried, Minimum 1000 TCID/50 per immunizing dose plus diluent	Single dose with syringe	$0.41
		Single dose without syringe	$0.33
		ten doses	$0.14
		50 doses	$0.14

Note: Unit prices are FOB Airport New York City suitably packed and iced for shipment to destination.

Section C - Shipping Instructions

1. The Contractor shall ship vaccine by insured air freight on prepaid bills of lading.

2. Shipping addresses of Member Countries for whom it is expected that most of the vaccine requirements will be ordered by PAHO are listed in ANNEX III of this contract. When PAHO places orders by telegraphic communications, these addresses will not be repeated in full. The Contractor will enter the appropriate shipping address as shown in ANNEX III, and the Purchase Order number and Purchase Authorization (P.A.) number provided in each PAHO order, on all shipping labels and shipping documents.

Best Available Copy

3. Forty-eight hours prior to shipment, the Contractor shall cable flight details to the consignee, with copy by cable to the Pan American Health Organization, ATT: APO Shipping Unit. The cable shall make reference to the PAHO Purchase Order number and the Purchase Authorization (P.A.) number shown in the PAHO order.

4. The Contractor shall book all connecting flights in advance and is responsible for insuring that vaccine is not held without proper refrigeration at trans-shipment points. If additional icing is required for destinations requiring trans-shipment, Contractor will be responsible to determine such need and to provide adequate additional icing.

5. If practical, vaccine should not be scheduled to arrive at destination during weekends and holidays.

Section D - Invoicing

The Contractor shall submit invoices for each shipment in original and four copies. Payment of air freight and insurance charges will be made at cost. Charges for air freight and insurance costs must be shown separately on the invoice and must be supported by a copy of the airway bill. Mail invoices to

Pan American Health Organization
525 Twenty-third Street, N.W.
Washington, D.C. 20037
Attn: APO (order number); (P.A. number)

Section E - Extension of Contract Period

The period of performance of this contract may be extended by mutual agreement of the contracting parties.

In WITNESS WHEREOF, the parties have executed this contract the date and year last below written:

PAN AMERICAN HEALTH ORGANIZATION

BY Walter Howard

(date)

CONTRACTOR

BY E. O'Hara

Jan 2 1979
(date)

Please sign and return one copy of this contract to indicate acceptance to:

Pan American Health Organization
525 Twenty-third Street, N.W.
Washington, D.C. 20037
Att: APO

Best Available Copy

Dr. SARETT. The situation where we have gotten into competitive bidding in the past is one in which we have not been able to compete very successfully. Because of some of the reasons that the PAHO experts mentioned, we have tried to stay in it. Reasons such as continuity of production and reasons of pride, perhaps, went against economic good sense.

But, as I mentioned earlier, the trends in recent times have shown that we are not successful in this international bid business; that we cannot bring in bids that are low enough to compete successfully with, in many cases, the subsidized foreign producers.

Senator HAWKINS. Don't you have a deep sense of responsibility to your own Government?

Dr. SARETT. Certainly, we do; we do indeed. I think that is demonstrated by our continued good relationship with the CDC, which Mr. Morr described earlier.

Senator HAWKINS. On a broader scale, how do you explain that, during 1979 to 1982, the international price for measles rose about 15 percent, while Merck Sharp & Dohme's U.S. price increased 60 percent?

Dr. SARETT. There are different factors governing that. The bid price overseas certainly is under different constraints than the U.S. price. Probably, in many cases, there was overzealousness which can cause mistakes. We have decided to put in a bid for whatever reason—reasons that I mentioned earlier—and I think those things will not continue.

Senator HAWKINS. In 1982, which is rather current, the U.S. price was 380 percent higher than the international price. How do you explain that?

Dr. SARETT. Mr. Morr?

Mr. MORR. I do not know which international price you are talking about.

Senator HAWKINS. The Pan American Health Organization contract price.

Mr. MORR. OK. Let me point out that there is a difference. In the case of PAHO, they were buying it with the syringe; they were buying huge volumes of material. As we stated earlier, the primary package that is purchased in the United States by the Centers for Disease Control is MMR. That is not measles by itself.

In the case of measles—and I have the numbers in front of me—our CDC price back in 1978–79 may have been for a different package. I am not sure which package we are talking about. Our price to the CDC was based on much smaller volumes. Although I do not have the CDC volume numbers here, I know we are talking about less than half a million doses, and PAHO mentioned they were talking about 5 to 9 million doses.

Our price in the United States was 87 cents a dose when their price was 41 cents a dose.

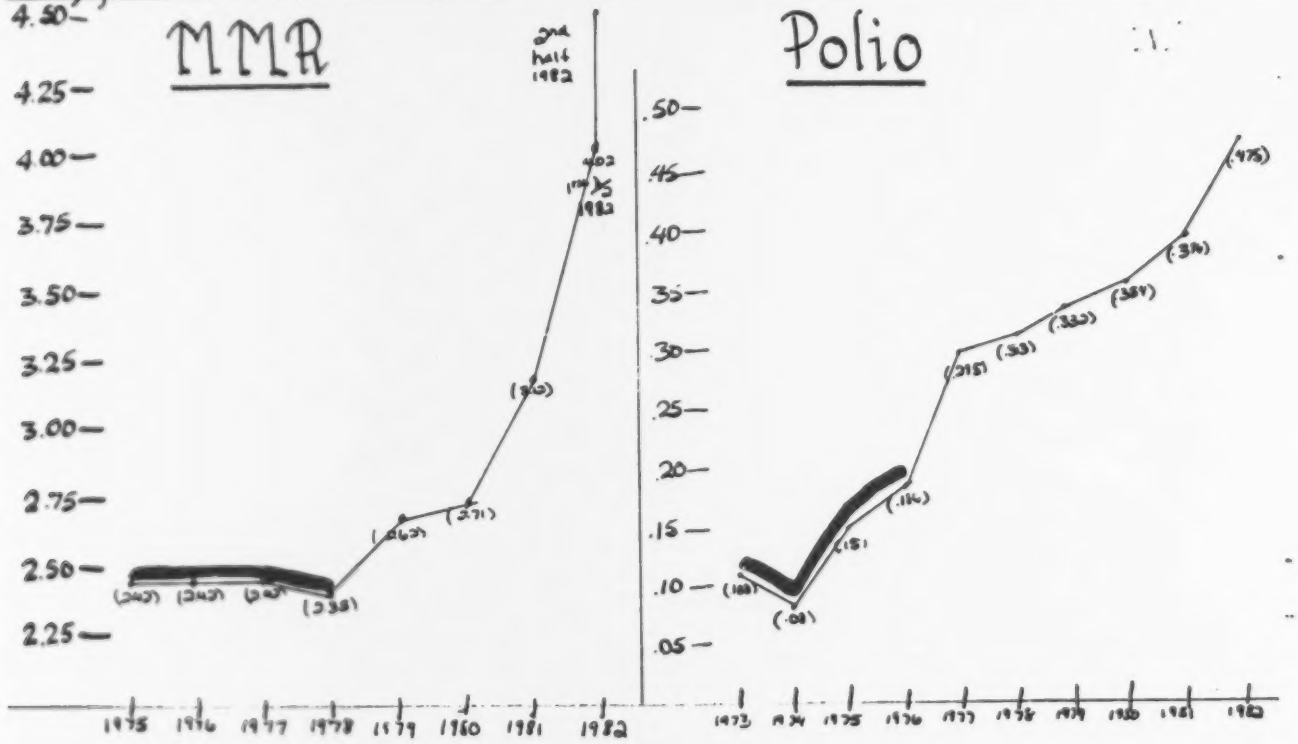
Senator HAWKINS. Well, Dr. Sarett, in addition, Pan American Health Organization representatives told us this morning that Merck sold small lots of measles and rubella vaccine in June and October of 1981. One order was for 10,000 doses, and another for 15,000 doses. For both contracts the price per dose was 93 cents. These orders included syringe and needle and diluent in lots of 10.

Your price for measles and rubella vaccine in 1981 sold to the CDC was $1.89. Why was that?

[The purchase order referred to follows:]

Best Available Copy

Effect of Competition On Vaccine Prices



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VACCINE	VIAL SIZE	PRICE PER DOSE (FOB AIRPORT) * TOTAL QUANTITY	PRICE PER DOSE (FOB AIRPORT) * 1/2 TOTAL QUANTITY	PRICE PER DOSE C.I.F. MEXICO CITY MEXICO	PRICE PER DOSE C.I.F. BOGOTA COLOMBIA	PRICE PER DOSE C.I.F. B.AIRES ARGENTINA	SHIPPING WEIGHT INFORMATION (INDICATE N° OF VIALS & GROSS WEIGHT OF FULL SHIPPING CONTAINER INCLUDING ICING) NUMBER VIALS	GROSS WEIGHT
Measles Vaccine, live, attenuated, freeze dried minimum 1000 TCID/50 per immunizing dose plus diluent.	Single dose (with disposable syringe and needle incl)	$0.41	$0.53	$0.44	$0.448	$0.485	SYRINGES ONLY 1000 Syringes	21 lbs.
	Single dose (without syringe and needle)	0.33	0.45	0.35	0.356	0.38	2000	75 lbs.
	10 dose	0.14	0.25	0.147	0.15	0.158	720	69 lbs.
	50 dose	0.14	0.21	0.16	0.165	0.18	240	75 lbs.
	Other (specify)	--	--	--	--	--	--	--

DELIVERIES: (1) Number of weeks after receipt of order that deliveries can be made two to three weeks.

(2) Latest date order can be received for company to make deliveries in February and March 1979 early December 1978

ESTIMATED QUANTITIES TO BE ORDERED (DOSES)

Vial size	1st. quarter	2nd. quarter	3rd. quarter	4th. quarter	Total
Single dose	2,406,000	1,041,000	1,526,000	477,000	5,450,000
10 dose	1,599,000	1,587,000	646,000	644,000	4,476,000
50 dose	400	400	400	400	1,600
				TOTAL	9,927,600

* SEE ATTACHMENT III FOR FURTHER DETAILS AND CONDITIONS OF THESE QUOTATIONS.

ANNEX I
PAGE 1 OF 4

PAN AMERICAN HEALTH ORGANIZATION
Pan American Sanitary Bureau · Regional Office of the
WORLD HEALTH ORGANIZATION
525 Twenty-third Street, N.W. Washington, D.C. 20037
CABLE ADDRESS: OFSANPAN • Telephone (202) 861-3200
Intl. Telex RCA 248338, ITT 440057, WUI 64152
Domestic Telex 892744

MERCK, SHARP & DOHME INT.
Post.Office Box 2000
Rahway, New Jersey 07065

Attn.: Dept. P33-67

PURCHASE ORDER
APO- 80725 BM

DATE 29 June 1981
FUNDS AVAILABLE | COMM. NO.
AUTHORITY PA EPI 053
☐ PARTIAL ☐ FINAL

ALLOTMENT	ELEM.	OBLIG. #	EXP. CODE	AMD.	OBLIG. AMOUNT	DESCRIPTION (APO# AND VENDOR)
81/PO/AMRO/0170					$ 9,300	80725 MERCK, SHARP & DOHME

Materials or services described herein are to be delivered for the account of Pan American Health Organization in accordance with the general conditions and instructions set forth below and on the reverse side of this order.

ITEM NUMBER	DESCRIPTION	QUANTITY	UNIT	UNIT PRICE	TOTAL AMOUNT
1	Combined measles-rubella vaccine, lyophilized. Single dose vials, syringe with needle, plus diluent in 10 dose vials.	10,000	Dose	$ 0.93	$ 9,300
	Total CIF San José Costa Rica via air shipment.				
	Quotation: Telephone Mr. Lauria to Mrs. Midence on 29 June 1981				
	Delivery: On or before 2 August 1981 - URGENTLY REQUIRED				
	Ship to: REPRESENTANTE OPS/OMS EN COSTA RICA Apartado OPS/OMS, Tel. 216458, Tlx 2568 San José, Costa Rica Attn.: APO 80725: PA 080 (EPI 053)				
	Ship via: Insured air freight prepaid on international through airwaybill				
	Inquiries concerning this order should be addressed to our Shipping and Expediting Unit at (202) 861 3436				

Sheet 1 of 1 Sheets BM:mbg

W.W. IRSTEAD
CONTRACTING OFFICER

Best Available Copy

PAN AMERICAN HEALTH ORGANIZATION
Pan American Sanitary Bureau - Regional Office of the
WORLD HEALTH ORGANIZATION
525 Twenty-third Street, N.W. Washington, D.C. 20037
CABLE ADDRESS: OFSANPAN • Telephone: (202) 861-3200
Intl. Telex RCA 248338, ITT 440057, WUI 64152
Domestic Telex 892744

PURCHASE ORDER
APO- 80791 (Bh)

DATE 6 October 1981

FUNDS AVAILABLE	COMM. NO.
AUTHORITY	P.A. 080 (EPI-076)
☐ PARTIAL	☒ FINAL

TO:
Merck, Sharp & Dohme, Int.
Post Office Box 2000
Rahway, N. J. 07065

Att: Dept. R33-67

ALLOTMENT	ELEM.	OBLIG.#	EXP. CODE	AMD.	OBLIG. AMOUNT	DESCRIPTION (APO# AND VENDOR)
81/PQ/AVR/0170	50		5900		$ 13,950.	80791 Merck, Sharp & Dohme, Int.

Materials or services described herein are to be delivered for the account of Pan American Health Organization in accordance with the general conditions and instructions set forth below and on the reverse side of this order.

ITEM NUMBER	DESCRIPTION	QUANTITY	UNIT	UNIT PRICE	TOTAL AMOUNT
	Combined measles-rubella vaccine, lyophilized. Single dose vials, syringe with needle, plus diluent in 10 dose vials	15,000	dose	$ 0.93	$ 13,95(
	Total CIF San Jose, Costa Rica, via air freight				
	Quotation: Telephone Mr. Le.ris to Mrs. Kidence, 22 September 1981				
	Shipment: On or before 17 November 1981				
	Ship to: Representante OPS/OMS en Costa Rica Apartado OPS/OMS P. O. Box 3745 San Jose, Costa Rica Att. APO-80791 (Bh) AC 080 (EPI-076)				
	Tel. 216 458 Telex 2568				
	Ship via: Insured air freight prepaid on international through airway bill				

"The Government of Costa Rica requires that invoices for imported supplies describe in Spanish the contents of each shipment. It is requested that an invoice be prepared for this purchase order. It is not necessary for the invoice format to be in Spanish; however, it is necessary that the description of each item contained in the shipment be inSpanish.

Inquiries concerning this order should be addressed to the Shipping and Expediting Unit at (202) 861 3436.

Sheet 1 of 1 Sheets

Walter R. Thurlow, CONTRACTING OFFICER

Best Available Copy

Mr. MORR. I am not sure which countries you are talking about. I know some of those have gone to Nigeria; some have gone to the lesser developed countries.

Senator HAWKINS. This is for Costa Rica. This is purchase order APO-80791, dated the 6th of October, 1981. It went to San Jose, Costa Rica, for 15,000 doses at 93 cents—a total of $13,930.

Mr. MORR. I think it gets back to what Dr. Sarett was talking about earlier, which is that in the lesser developed countries, we feel some responsibility to provide vaccine for those people who may need it, in fact, more than some children in the United States.

Senator HAWKINS. Mr. Bowman, the same pattern is true with polio, although I understand you have never bid for the PAHO contract.

Mr. BOWMAN. Right.

Senator HAWKINS. Why have you not bid for the international contract?

Mr. BOWMAN. There are some secondary reasons, such as, we do not really have the manufacturing capacity to add another 31 million doses. We are sized for the U.S. market—23 million doses. We could make 35 if we had to; we could not handle PAHO.

But the main reason is the way we make and the way we test polio vaccine is different from the way it is done anywhere else in the world, and it costs a lot more. It sounds flippant, but it is a matter of monkeys.

Senator HAWKINS. A matter of what?

Mr. BOWMAN. Monkeys; yes, indeed. The way that it must be done in the United States requires neurovirulence testing using rhesus monkeys. We use about 1,000 of those a year. The price of those monkeys went from about $200 in 1978 to $1,000 to $1,200 now.

Senator HAWKINS. Where do you buy the monkeys?

Mr. BOWMAN. If you know a good source, we would appreciate it. [Laughter.]

Mr. BOWMAN. It is extremely difficult. The Indian government has——

Senator HAWKINS. How about Costa Rica? [Laughter.]

Mr. BOWMAN. We scour zoos, and the Federal Government provides some, and also we try to grow our own. We established a colony with about 3,500 monkeys in Texas. But while this sounds kind of trivial, the fact of the matter is that it adds very substantially to the cost of making vaccines in the United States.

I think it is money well spent, because the best assurance possible is needed on neurovirulence. To administer a vaccine that has some potential for actually causing the disease which it is meant to prevent, and when that disease is poliomyelitis, it is worth a few cents more.

We cannot make and sell vaccines at the price that PAHO can get them.

Senator HAWKINS. So that accounts for the international price being 3 cents a dose, while the U.S. price was 47.5 cents per dose?

Mr. BOWMAN. Right.

Senator HAWKINS. And that is principal reason?

Mr. BOWMAN. A very big reason is the way we make and manufacture it. There is also the fact that—well, perhaps I will not get

into that area. I was merely going to comment that we do not have the need to dispose of surplus capacity, which many manufacturers in other countries have to do. They want to run their plant full; their plant is too big for their country, so they must drop the price somewhere.

Our plant is sized for the United States. We do not have the need to dispose excess vaccines elsewhere.

Senator HAWKINS. Dr. Sarett, since you are this Nation's only source of MMR vaccine, is it important for all of us here today to know if you have ever considered leaving the market?

Dr. SARETT. Well, we most certainly have considered leaving the vaccine market entirely. We think about it every year. I would have to say that in terms of economics, that segment of the industry that serves health in the United States—of all those segments, the vaccine business is the most precarious, the most fragile, and the most likely to go under. So, we most certainly have thought about it.

I would add to that, that however worthy the motivation in examining the pricing details of vaccines, there is a grave danger, in my opinion, of discouraging an industrial segment which, by and large, has provided more to health in the United States than any other segment. I think what we need, truly, is encouragement in vaccine research rather than discouragement.

Senator HAWKINS. What would happen if you left the market?

Dr. SARETT. Well, a number of Federal executives have repeated to us on many occasions that, in their opinion, we have a national responsibility, and we see it the same way. That is one of the reasons that we have stayed in, even though the economics, as we have looked at them and as we have tried to evaluate them, have been discouraging.

What would happen? I think that there would be some severe readjustments that would have to be made on the part of our public health programs, and so I do not think, unless circumstances turn more adverse than they are now, that we will leave. We have a dedication and we are very proud of the contributions we have made and it would take a lot to turn us off, but it is not impossible that it could happen.

Senator HAWKINS. How long would it take another manufacturer to fill the void if you were to make the decision to leave?

Dr. SARETT. Well, if we were to turn over all of our knowhow, then it would take him as long as it does to build facilities—dedicated facilities, in some cases. It would take him the time to tool-up and to educate the staff. I think you are talking about a matter of years, not months.

Senator HAWKINS. Two years?

Dr. SARETT. Perhaps.

Senator HAWKINS. Mr. Bowman, what is Lederle's position regarding its commitment to providing polio vaccine in the United States?

Mr. BOWMAN. We fully intend to continue providing polio vaccine. The one straw which could break the camel's back would be some serious escalation of our product liability problems. I do not think that is going to happen. If it did, however, and if we simply

could not afford to stay in the business, we would phase ourselves out of it in such a way as to assure continued availability.

We maintain an 18-month supply of oral polio vaccine in various advanced stages, and certainly would not abandon the manufacture of the vaccine until other sources were guaranteed for the population.

Senator HAWKINS. Could you develop the capacity to manufacture MMR if Merck left the market?

Mr. BOWMAN. Perhaps Dr. Cano could respond to that.

Dr. CANO. In answer to the question, yes, we could. We did have a mixo-virus program in the 1970's where we expended more than $4.5 million to develop a measles, mumps and rubella program, but we decided to get out of that business.

Senator HAWKINS. How long would it take you to get into the business if you had to?

Dr. CANO. I would have to answer the question the same way as Dr. Sarett. It would take us the time to build the facilities. I think we would have the added advantage of having the technical expertise there, but we still would have to build facilities, which would have to take a period of at least, I would say, 2 years.

Dr. SARETT. Of course, if I may add a word, Senator Hawkins, to that.

Senator HAWKINS. Dr. Sarett?

Dr. SARETT. When you transfer the knowhow and transfer equipment, you are leaving behind the vital part, which is the research for the vaccines of tomorrow. That would simply be a casualty of any hypothetical transfer of that sort.

Senator HAWKINS. Mr. Bowman, I am impressed by your public commitment to continue to provide polio vaccine to this country. I, for one, know how terrible that disease is. Our son had polio in the third grade and was completely paralyzed for 1 year.

Mr. BOWMAN. That is too bad.

Senator HAWKINS. But through a lot of tremendous therapy he is well, except for a slight limp. His recovery was a great blessing for our family.

I want to thank all you gentlemen for your testimony. I appreciate your taking time to testify before this subcommittee. We are at stage one of an ongoing investigation of this vital subject. Because it is mandated by most States that our children be immunized before they attend school, and because Congress just increased the immunization appropriation, the matter must be resolved.

I will excuse this panel at this time and call our third panel of witnesses.

Dr. SARETT. Thank you.

Senator HAWKINS. Thank you so much for coming.

Our third panel will consist of various State health officials who will testify about the State programs operations. We have Dr. Stephen King with us, who is from my home State of Florida and relatively new in his assignment. Next, we have Dr. Dale Morris, Bureau of Communicable Disease Control, from New York State; and Mr. Donald Biemiller, program coordinator of the immunization program for the State of Virginia. Mr. Biemiller is accompanied by Dr. Lao, who is procurement officer of the division of purchasing.

Mr. LAO. I am not a doctor.

Senator HAWKINS. You don't want to be a doctor today? You missed your chance.

I will start with Dr. King. We appreciate your coming to help us today. Can you explain to us the purchasing procedure for vaccines in Florida?

STATEMENT OF STEPHEN KING, HEALTH PROGRAM OFFICE, DEPARTMENT OF HEALTH AND REHABILITATIVE SERVICES, TALLAHASSEE, FLA.; DALE MORRIS, BUREAU OF COMMUNICABLE DISEASE CONTROL, STATE DEPARTMENT OF HEALTH, ALBANY, N.Y.; AND DONALD BIEMILLER, PROGRAM COORDINATOR, IMMUNIZATION PROGRAM, RICHMOND, VA., ACCOMPANIED BY LEONARD LAO, PROCUREMENT OFFICER, DIVISION OF PURCHASING, RICHMOND, VA.

Dr. KING. Yes, I would be glad to do so. The State determines on an annual basis the anticipated needs for the various vaccination materials. The anticipated cost for this is included in a budget item in the State general revenue budget. It includes more than just the immunization materials, however. It includes the drugs that are used in a variety of programs, such as the tuberculosis program, the rheumatic fever program, the programs for epilepsy and venereal disease. That budget is of general State revenue.

There is also in the State a State pharmacy committee, which is established by the secretary of the department of health and rehabilitative services, which meets on a regular basis, considering additions or deletions to the State pharmacy. There is a State pharmacy, which is the repository for these drugs and vaccination materials from which the various county health units and other public agencies draw over the course of the year.

The determination as to the approximate numbers of doses and the forms in which these doses are anticipated to be needed in the State is communicated to the department of general services, and they then, knowing the approximate number of doses that we need, let it out on a bidding process.

Some of the vaccination materials, we presently purchase through the Centers for Disease Control, and those are largely the live viruses. The nonlive viruses, such as the DPT and the various subunits of that, and also rabies and gamma globulin and other materials, are obtained on a general State contract.

Senator HAWKINS. What are the sources of the funds used to purchase these vaccines?

Dr. KING. The source of funds for vaccines in Florida, to the best I have been able to research that issue, for a number of years has been State general revenue.

Senator HAWKINS. Are any items purchased with the Federal dollars?

Dr. KING. The Federal grant, which is the immunization grant which is received by the State from the Federal Government, is used, I believe, almost exclusively, to support immunization staff. These are people who supervise, coordinate, and direct the immunization program around the State.

The support comes in two forms. One is what is called direct assistance, and that is the assignment of three Federal assignees. They came to the State in lieu of a portion of those dollars in the immunization award. And the rest of those are in State positions and are funded out of the Federal grant.

Senator HAWKINS. Do you presently buy all of your measles, mumps, rubella and polio vaccines at Federal CDC prices?

Dr. KING. Yes, we do.

Senator HAWKINS. I know you are new in your position; I have mentioned it several times. We had hoped that the State purchasing official with the direct responsibility for the past contract negotiations would appear, but I understand that will not be possible.

Dr. KING. I would be glad to help, Senator, if I could.

Senator HAWKINS. I must inquire about the information provided to us by the State purchasing office. When did you begin purchasing these vaccines at Federal prices?

Dr. KING. Where we are talking about the live vaccines, they were begun to be purchased in 1978, but the majority in 1979.

Senator HAWKINS. Did it result in savings to the State of Florida?

Dr. KING. That is one of these questions where the answer is both yes and no. The per-unit dose price for the 2 years, approximately, prior to that time that the vaccines were available from the CDC when the State was purchasing through the State contract with the private providers was a higher price on a per-unit dose basis than was available through the Centers for Disease Control.

However, the other answer to that is no. I do not believe that, necessarily, I would agree that it cost the State of Florida or the Federal and State taxpayer more money in the aggregate because of certain expenses during those 2 years which, in all likelihood, would have increased the total cost of the program because of requirements on the part of the Federal Government.

A couple have already been mentioned; one of them is the "no return" policy. The county health departments in the State of Florida are relatively autonomous; they are not directly administered by the State agency. As a consequence, when the pharmacy responds to an individual county's request for vaccine, it may well be an exaggerated request and there would be a good deal of returned vaccine.

The other issue, beginning in about 1977 or 1976, there was a requirement on the part of the Federal Government through the CDC—something I think was personally appropriate—that there be an informed consent in each individual case of a vaccination provided in county health units.

That in formal consent had not been traditionally the case. In almost every State in the country, there was a general consensus that there was implied consent when an individual came to the health department for his immunizations; that there was not the need to get involved in individual counseling and implied consent.

If the State of Florida had gone, in 1977, let us say, or 1978, to the CDC's contract, the cost to the State perhaps would have been in the case of polio—I looked at it briefly—about $20,000 less for polio that year, had we used the CDC price versus the bid price we had in the State.

But the costs to the State in terms of downtime for staff for education, for purposes of printing, and for getting the whole legal process necessary to have an appropriate implied consent, would have been quite costly in terms of time and energy of persons involved.

Now, by 1979, it became clear that the differential in price in 1978 was significant enough that that increased cost we could not continue to bear. And there was a changed appreciation, I think, around the country to the fact that it is appropriate to have informed consent, whether it is a public agency or a private agency.

Senator HAWKINS. It is my understanding that prior to 1978, the State purchasing agent was not aware that the price was lower.

Dr. KING. That the price was different?

Senator HAWKINS. The CDC price.

Dr. KING. I do not believe it was, prior to 1978, significantly different. Now, maybe it was, but I cannot answer that question. I am sorry.

Senator HAWKINS. The figures I have show that in 1978 the State of Florida paid 43 cents for each dosage of polio vaccine and $2.63 for each dose of MMR vaccine, while the CDC prices were 31 cents and $2.35.

Dr. KING. That is correct. In 1978, we were aware of it. I am sorry; I misunderstood you. I thought you had asked me about prior to that time. In 1978, from the people that I have talked to that were there and involved in the process, it was the beginning of the time that they came to be aware that the price was significantly different.

Senator HAWKINS. Do you annually receive a memo from the CDC listing their contract price? The reason I ask is that I have been led to believe that this is the case. Indeed, I have some sample copies in front of me.

[The sample copies follow:]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL
ATLANTA, GEORGIA 30333
TELEPHONE: (404) 633-3311

October 10, 1978

RECEIVED
OCT 13 197
BUREAU OF
DISEASE CONTRO

Dr.
Director
Division of Preventable Disease Control
Mississippi State Board of Health
P.O. Box 1700
Jackson, MS 39205

RECEIVED
OCT 16 '78
IMM. PROG

Dear Dr.

A new contract has been awarded for the supply of the below l vaccines. You are authorized to purchase these vaccines with Federal funds other than immunization grants against the follow ing contract:

Contractor:

Merck, Sharp & Dohme
Division of Merck, Inc.
West Point, PA 19486

Contract:

V797P-5591e, effective October 2, 1978 through October 1, 1979.

Prices:

Rubella Virus Vaccine, Live	
Single dose with syringe & needle	$.94/dose
Ten dose vial	.61/dose
Fifty dose vial	.57/dose
Attenuated Rubeola-Rubella Vaccine, Live	
Single dose with syringe & needle	$1.58/dose
Ten dose vial	1.24/dose
Fifty dose vial	.85/dose
Further Attenuated Rubeola Virus Vaccine, Live	
Single dose with syringe & needle	$1.12/dose
Ten dose vial	.86/dose
Fifty dose vial	.57/dose

Best Available Copy

Prices: (cont'd)

Mumps Virus Vaccine, Live	
Single dose with syringe & needle	$1.60/dose
Ten dose vial	1.21/dose
Measles, Mumps and Rubella Virus Vaccine, Live	
Single dose with syringe & needle	$2.62/dose
Ten dose vial	2.07/dose

Copies of all purchase orders issued under this authorization should be forwarded to:

Center for Disease Control
Bureau of State Services
Immunization Division
1600 Clifton Road, N.E.
Atlanta, GA 30333

Sincerely yours,

David K. Rowe
Director
Procurement & Grants Office

Best Available Copy

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
Atlanta, Georgia 30333

May 10, 1982

Dr.
Chief
Bureau of Disease Control
Mississippi State Board of Health
P.O. Box 1700
Jackson, MS 39205

RECEIVED
MAY 14 1982
IMMUNIZATION PROGRAM

Dear Dr.

Please be advised that the current contract with Merck, Sharp and Dohme has been extended through December 31, 1982. New vaccine prices will be effective May 1, 1982, as follows:

CONTRACTOR		CONTRACT
Merck, Sharp and Dohme Division of Merck & Co., Inc. West Point, PA 19486		V797P-5653(g) Effective 10/15/81 Thru 12/31/82
Product	**Packaging***	**Price**
Live, Rubella	Single dose	$1.61/dose
Measles, Mumps, Rubella	Single dose 10 dose vials	4.50/dose 3.45/dose
Live, Further Attentuated Rubeola	Single dose	1.90/dose
Live, Attenuated Measles-Rubella	Single dose	2.72/dose
Live Mumps	Single dose	2.70/dose

*A minimum of 500 doses per antigen must be ordered on a single order.

When ordering under the optional use provision of the contract, please forward one copy of the order to:

Centers for Disease Control
Center for Prevention Services
Immunization Division
1600 Clifton Road, N.E.
Atlanta, GA 30333

Sincerely yours,

David K. Rowe
Director
Procurement & Grants Office

Best Available Copy

Dr. KING. I have not personally received one. That information is available to us on a regular basis through a number of means. In 1978, when the price differential really began to spread, we had an obligation at that point for 100,000 doses, so that it was not possible for a period of several months to begin the process of making the actual change.

I think the state became acutely aware of the spreading price differential toward the end of fiscal year 1978. Now, I have some information that might point to the difference in prices prior to that time. It was my impression that they were——

Senator HAWKINS. Did the State of Florida at that time have a Federal CDC employee working in the State program?

Dr. KING. Yes, Senator. There has been a Federal employee in the State, to my direct knowledge, since 1963.

Senator HAWKINS. Since 1963?

Dr. KING. Yes. As a matter of fact, the State health officer in 1940 in Florida was an assignee from the Public Health Service.

Senator HAWKINS. Did the Federal CDC employee bring the reduced CDC prices to the attention of State officials, to your knowledge?

Dr. KING. To my direct knowledge, I do not know. In discussing it with the people who were involved at that point in time, there was a great deal of discussion between 1977 and 1978 as to whether or not to accept the decreased cost and go with the consent and the nonreturn policy. And the decision, I am quite certain, in that 2-year period of time to not take the CDC price was tied to the two major problems of nonreturn and consent. So, the answer to your question is, yes, there must have been discussion.

Senator HAWKINS. Is it not one of the problems that the State purchasing agent in Florida has a tremendous amount of responsibility? He told my staff that he negotiates between 85,000 and 90,000 contracts per year for a wide variety of goods. In fact, he wanted to talk to them quite at length about tires, but we really were not interested in tire purchasing. Is that correct?

Dr. KING. I do not believe so, Senator. I had a discussion with the gentleman in preparation for the visit here this morning, and I asked him specifically how many contracts he had. He told me that he had 29 contracts, 10 of which were 10 separate drug contracts, the rest largely being in automobiles and supplies, as you mentioned, and hospital supplies and laboratory supplies.

That amounts to approximately $16 to $20 million worth of contract business that this particular individual who is responsible for all of our drugs and hospital supplies and laboratory supplies has as his direct——

Senator HAWKINS. This is a particular individual for hospitals and drugs that you are talking about now?

Dr. KING. Mr. Glover, yes.

Senator HAWKINS. Not the State purchasing agent, per se?

Dr. KING. No. The State purchasing division—I would not be surprised but that it is that great. The State does a great deal of contracting in a whole variety of areas.

Senator HAWKINS. Maybe Mr. Glover was referring to the whole division when he cited the 85,000 to 90,000 contracts Mr. Glover told my staff that he could not get particularly excited about indi-

vidual contracts because he negotiates so many that this was very miniscule on the total range.

Dr. KING. Well, I hope that Mr. Glover—and I am certain now, from our discussions in the last 2 or 3 days—will continue and, if necessary, increase his interest in this process.

Senator HAWKINS. I am hopeful that he will, also.

On chart IV, we show you that Florida in 1981 paid 18 cents per dose for 200,000 units of DPT vaccine, while the State of Virginia bought half that amount at only 12 cents per dose. Both purchases were made from the same manufacturer. The Florida purchasing agents could not provide us or the staff with any explanation for the price disparity. I wonder if you have any insight into this significant difference.

Chart IV referred to maybe found on p. 7.

Dr. KING. I do not have enough insight to satisfy me completely at the present time, and I can only respond to what would normally lead to differentials in prices between States, one of the main being, again, the nature of the program in individual States.

One of the States could have had a very large push across a large part of the State covering that particular budget year, and as a consequence was able, through the nonreturn policy and very large quantities, to purchase at a significantly different price than the State of Florida, which has not yet in that area been willing to accept a nonreturn contract.

But I must admit that that does seem like a wide differential, and I cannot adequately explain it.

Senator HAWKINS. In 1981, the chart illustrates that Florida's price for DPT dropped by one-third.

Dr. KING. Yes.

Senator HAWKINS. Do you know why?

Dr. KING. Part of it, again, was the numbers, and perhaps it was related to—I see the thrust of your question, and I cannot explain that adequately. I am glad that it went down. I still do not understand that single peak in 1981. Without that peak, it follows generally the rest of the crowd, and I do not understand completely the peak in 1981.

Senator HAWKINS. Do you know if the State purchasing agent compares vaccine prices with other States?

Dr. KING. I do not know that for a fact. I do know that there is an organization of State purchasing agents which has a fairly good communication network. One of the things I learned, and it was very pleasing to me, in my discussion of how they, in fact, did do their business is that there is fairly significant communication, not specific to immunization costs, I do not believe, but to the whole purchasing business that State agencies are in; also, the fact that they are very actively involved in a Federal quality assurance program which is fairly recent in its institution.

A number of States have begun, in a cooperative effort with the Food and Drug Administration, to take part in regular sampling on a random basis of the efficacy and quality of the agents that are being purchased, and that is something that this organization is in the process of doing. And I think that speaks, even though perhaps it is a recent occurrence, to questions and concerns of quality, cost efficiency and effectiveness.

Senator HAWKINS. Does Florida require that all schoolchildren be immunized?

Dr. KING. Yes, it does. The law has evolved over the years, but the latest statute passed by the Florida Legislature requires—and it is a fairly stiff law; that no one is allowed in the school without some medical excuse this year at all, and that is kindergarten through the 12th grade.

In my recent move to Florida, this directly affected me. Two of my children are still remaining at home, one of whom is an adolescent and will require measles vaccine because his original measles was outdated.

Senator HAWKINS. We are getting close to home.

Dr. KING. Yes.

Senator HAWKINS. I apologize; I have to go vote again. When we return, we will go to the New York State officials. We will just take a brief seventh inning stretch now.

[Whereupon, a brief recess was taken.]

Senator HAWKINS. Order, please.

Dr. King, I understand you have a statement.

Dr. KING. Yes, I do, Senator. One of the things that concerns me transcends the important issues before us. I think we are all obliged to use discretion in attempting to get the most that we can out of the federal and state dollars that are available to us.

But one of the things that occurs to me as a State health officer, and my understanding of what occurs in many States across the country, is that we are struggling yearly with an uncertainty as to from where the support for the immunization program is going to come.

I think every State health agency is responsible ultimately for the immunization status of its children, but it also seems to me to be very, very important in terms of the nation's health that that immunization status remain high and that it is sufficiently supported so that all of the states can continue to plan for and operate their programs effectively.

I am old enough and have been around for enough years that I can remember many of these kids that have been quite ill with diseases you simply do not see any more. The cost in human suffering and to families is something that is not behind us forever to be forgotten. It will come back; it will stay with us. The organisms are there.

Perhaps we can eliminate measles, but it will take a tremendous effort to do so. The State of Florida has gone from 300 cases to approximately 20 in 1 year, but that does not mean that so long as measles exists in the world that we are safe from it.

I would hope that in your deliberations, you and others would realize that it is a shared responsibility, and I sincerely hope that that concern becomes one which we can share together in the support of the program.

Senator HAWKINS. Yes. Well, the reason for the hearings is because of the keen responsibility we feel for this program. I have recently worked on the Senate floor to get more money for this program. This is one program that I do not believe should be block granted to the states. I feel that if we are going to continue the

child immunization program, we may have to earmark the funds to assure they are spent efficiently. We will see.

Dr. Morris, we welcome you from New York. Do you receive both State and Federal funds for your immunization program in New York?

Dr. MORRIS. Yes, we do. Good day. First of all, on behalf of the New York State Health Department, I would like to express our appreciation for being able to provide testimony today. We certainly do share your interest and support of the immunization program.

Yes, we do receive both State and Federal funds.

Senator HAWKINS. Do you buy all of your polio and MMR vaccines at the reduced CDC price?

Dr. MORRIS. We do not. We buy these vaccines with both State and Federal funds.

Senator HAWKINS. I could not hear your answer.

Dr. MORRIS. We purchase these with both State and Federal funds.

Senator HAWKINS. What percentage?

Dr. MORRIS. The exact percentage varies somewhat by time and by year of purchase. But, for example, if we take a 3-year time period, between July 1, 1979, and June 30, 1982, the New York State immunization program purchased 2,580,000,000 doses of polio, measles, rubella, mumps, MR and MMR vaccines, of which 661,000 doses—that is 25.6 percent—were purchased with State funds.

Senator HAWKINS. About 50-50 would you say?

Dr. MORRIS. Over the time period I described, it is slightly different. It was 25.6 percent with State funds, versus 74.4 percent with Federal funds. Now, that varies from time to time. At times, there would be times when it would be 50 percent; at other times, it would be less.

Senator HAWKINS. Dr. King has to leave, I understand, and we do not want you to miss your plane so we will excuse you at this time. Thank you so much for participating.

Dr. Morris, how long have you purchased in this fashion?

Dr. MORRIS. I do not have the historical perspective to tell you the exact time period. Certainly, over the past three years are the most accurate figures where the split——

Senator HAWKINS. What prices have you paid for MMR and polio?

Dr. MORRIS. Just a minute.

Senator HAWKINS. Yes.

Dr. MORRIS. Again, it has varied somewhat by time and by year. In terms of MMR vaccine prices—you are most interested in mumps and MMR?

Senator HAWKINS. Yes.

Dr. MORRIS. In terms of MMR vaccine prices, again it is varied by the contract time period. In the latest time period for the contract, effective date May 1, 1982, MMR vaccine for one dose was $4.50 on Federal contract prices.

Most recently, in terms of the state contract prices effective April 1—and this is buying in one to 10,000 doses—the price was $7.50. For mumps vaccine prices, the Federal contract price effective May 1, 1982, was $2.70 for single dose, while that for state con-

tract prices from April 1, when purchased in greater than 1,000, was $3.75. Part of the price difference depends on the volume that you would purchase.

Senator HAWKINS. According to the figures that you supplied the staff regarding the doses administered and the purchase prices, the amount of money that you would have saved had you taken advantage of the CDC prices for measles, mumps, rubella and polio is well over 1 million dollars over the last 5 years. Do you agree with that?

Dr. MORRIS. Those figures would be slightly different than what we would calculate. Again, part of that is more the time period. In terms of the doses which I gave to the 3-year time period, July 1, 1979, through June 30, 1982, in which there were 2,580,000,000 total doses of the vaccine and 661,000,000 doses which were purchased with State funds, an estimation of the difference of that—the price of a vaccine varies per dose on the contract price anywhere from 20 cents to $1.

So, we would make an estimate of a lower total—somewhere between 200,000 and 600,000.

Senator HAWKINS. Why do you not buy all of it at CDC prices?

Dr. MORRIS. There are several reasons why we do not. First of all, we could make, I guess, a pitch for more money. We do not have enough Federal funding to do so. Second, and what we would see as a most important issue, is the fact that we have found that we are unable to use State funds to purchase vaccine under the Federal contract.

This is different, for example, from within our own State where counties are able to purchase vaccine on the State contract price, and this certainly saves the counties tremendous savings. We would certainly like the ability to be able to use State funds to purchase vaccine under CDC contract prices.

Senator HAWKINS. Do you have CDC employees working in New York?

Dr. MORRIS. Yes, we do.

Senator HAWKINS. What is the role of these employees?

Dr. MORRIS. These employees work directly in the immunization program, which is mainly supported by categorical funds. The Federal employees are really the core of the immunization program in terms of three people do provide a lot of management responsibility over the program.

Senator HAWKINS. With the vaccines that are not available at CDC prices, such as DPT, is there any communication among State program and purchase people during the contract time?

Dr. MORRIS. I am sorry. Could you repeat that?

Senator HAWKINS. For the vaccines that are not available at CDC prices, such as DPT, is there communication among State program and purchase people during the contract time?

Dr. MORRIS. I do not know the answer to that question. I am not aware if there is. In our State at least, the negotiations for State contracts are not handled by the immunization program. They would be handled by a separate office, the office of general services from the State.

Senator HAWKINS. The office of general services?

Dr. MORRIS. Right. My understanding is that that is done on competitive bidding.

Senator HAWKINS. Have you ever examined what other States are paying for vaccines?

Dr. MORRIS. Personally, our program has not that I know of.

Senator HAWKINS. Do you plan in the near future to change your purchase procedure to save money?

Dr. MORRIS. We certainly always welcome new ways to save money, and certainly would welcome the opportunity. Again, one of the best ways we feel that that could be done is by giving us the ability to purchase vaccine under the Federal contract prices. We have also put in several other proposals, and this has been a recurrent theme that the program has put forward—supplemental budget requests—that several positions be taken over by State funding, which would free up more Federal funding.

Senator HAWKINS. There is no prohibition against your buying at CDC prices, is there?

Dr. MORRIS. Yes. Apparently, we cannot use State funds to buy at CDC prices.

Senator HAWKINS. Do you use all your CDC funds for a vaccine?

Dr. MORRIS. No, we do not.

Senator HAWKINS. What do you use that for, personnel?

Dr. MORRIS. It is used mainly for personnel, travel and other expenses.

Senator HAWKINS. Have you ever thought of using it just for vaccines?

Dr. MORRIS. That has been one thing that has been considered. At the present time, there would be no mechanism to maintain the personnel if we were to do so. For example, at the present time our immunization program is supported in three ways. The first major core of that is the categorical grant, which supports approximately 810,000 during a 1-year period of time.

We also utilize funds from title V, or the MCH block, which are used mainly to purchase vaccine. So, we try to utilize as much of that as possible to purchase vaccine. The third thing is from New York State local assistant funds.

It would be logistically very difficult for us to move the State funds to pay for personnel. I do not know whether other States share this same problem, but that would be very difficult, and I could go into that if you would like.

Senator HAWKINS. Well, let us see how Virginia administers its program.

Mr. Biemiller, do you receive State and Federal funds for your immunization program?

Mr. BIEMILLER. The main immunization program grant funds are received from CDC in support of personnel, travel, equipment, and certain other items to conduct the immunization program, as well as using CDC contract prices for the purchase of vaccines.

Senator HAWKINS. Do you buy all of your MMR and polio at CDC prices?

Mr. BIEMILLER. Yes, we do.

Senator HAWKINS. Why do you do it?

Mr. BIEMILLER. Well, I think that it is economically in the best interests of the State.

Senator HAWKINS. Is there any mechanism used by Virginia to insure efficiency in purchasing?

Mr. BIEMILLER. I would like to let Mr. Lao respond.

Senator HAWKINS. Mr. Lao?

Mr. LAO. Senator, we in Virginia hope we have a mechanism for efficiency in purchasing. I would like to say by looking at the charts over there that we inherited a legacy for being tough negotiators from Mr. Jefferson, but I cannot really say that.

But particularly in pharmaceutical purchasing, by utilizing expertise outside of the purchasing division, we do have a couple of panels that serve our division. One of those is a technical advisory panel, which is made up of pharmacologists from the University of Virginia and from the Medical College of Virginia. Their input to us is on the quality of the drug.

We also have a pharmacy advisory committee which serves our division. So, we do hope that through the expertise of these two committees, we do have efficiency in the purchase of drugs and pharmaceuticals in our State.

Senator HAWKINS. You are to be commended because your prices for DPT seem to be consistently low. How have you been able to keep these prices down?

Mr. LAO. That is a good question. I wish I could answer that.

Senator HAWKINS. I wish you could share that with us.

Mr. LAO. Well, I do not really know the reasons. There could be several reasons for it. Timing, as far as bid solicitation, could be a factor in this. It is my understanding that Virginia is one of the first States to solicit bids for contracts on drugs. And, of course, DPT is just one of the several thousand drugs that we solicit bids on for our annual drug contract.

I wish I knew the answer to why we get the low prices; I really do not.

Senator HAWKINS. Mr. Lao, do you have any background in pharmaceutical products?

Mr. LAO. Absolutely none.

Senator HAWKINS. Maybe that is the secret.

How many contracts do you negotiate for the State of Virginia?

Mr. LAO. Personally, or our division?

Senator HAWKINS. Personally.

Mr. LAO. Up until January of this year, I did negotiate the pharmaceutical contract, and probably only about three others. Now, I am talking about annual term contracts.

Senator HAWKINS. So, they were almost all medical?

Mr. LAO. They were all in the medical area, yes. Our division handles some, I would say, 250 to 300 term contracts for other commodities.

Senator HAWKINS. Nonmedical?

Mr. LAO. Nonmedical.

Senator HAWKINS. How important is a liberal return policy for State supplemental purchases of vaccine?

Mr. LAO. Well, I think it is important. I am really not sure how important it is. If users know their needs, you know, maybe it is not that important to have that returned goods policy. But knowing the usage of drugs, and so forth, in the State, I would have to

say probably that most firms do have a liberal returned goods policy.

I know in the earlier testimony from Merck, they mentioned that beginning in May of 1982, they were going to change their returned goods policy on vaccines. Of course, we are in the middle of a contract period with Merck right now on MMR, which begin in January of 1982. I guess we will find out, come 1983.

Senator HAWKINS. You will let us know?

Mr. LAO. Yes.

Senator HAWKINS. I really appreciate you gentlemen helping us here. I think it is important to note that we surveyed a smattering of States. I really want to commend Virginia for the great job that they do, and we probably will ask you back at another time. Thank you so much for appearing here today.

At this time I call up Panel 4. We would like to welcome back Dr. Alan Hinman, who is Director of the Immunization Division for the CDC. Dr. Hinman testified before this subcommittee on May 7 at our first hearing on the national childhood immunization program. We want to thank Dr. Hinman for his continued willingness to assist Congress in its oversight responsibilities.

It was his suggestion that we have this hearing. Last May he said if we wanted to know why prices were going up so much, we ought to ask the manufacturers. We have been doing that today.

With Dr. Hinman is Mr. David Rowe, Director of the Procurement and Grants Office; Mr. Dennis Styrsky, Chief, Marketing Division for Pharmaceutical Products of the Veterans' Administration; and Don Stenhouse.

Dr. Hinman, what is the procedure used in purchasing vaccines that we have been discussing today?

STATEMENT OF ALAN R. HINMAN, DIRECTOR, IMMUNIZATION DIVISION, CENTER FOR PREVENTION SERVICES, CENTERS FOR DISEASE CONTROL, ATLANTA, GA., ACCOMPANIED BY DAVID ROWE, DIRECTOR, PROCUREMENT AND GRANTS OFFICE, CENTERS FOR DISEASE CONTROL; DENNIS STYRSKY, CHIEF, MARKETING DIVISION FOR PHARMACEUTICAL PRODUCTS, VETERANS' ADMINISTRATION; AND DONALD STENHOUSE, ACTING CHIEF, PROGRAM OPERATION SECTION, IMMUNIZATION DIVISION, CENTERS FOR DISEASE CONTROL

Dr. HINMAN. Senator, if I could just take a second and express to you our gratitude at being here, and also, since you have asked that we not read from a prepared testimony, ask that you accept our testimony for the record.

Senator HAWKINS. Yes; we would be happy to. We have to vacate the room; our rent is up shortly.

Dr. HINMAN. I would also like to make, if I may, three very quick points. First, we are very pleased with the progress that has been made in this country in the conquest of childhood diseases, and second, we are very proud of the role the Federal Government has played in helping accomplish that, in part, through the Federal consolidated contract for the purchase of vaccines, with which we have saved about $100 million over the last 5 years. I think that that is a remarkable accomplishment.

Third, there are ways in which this purchase could be improved, and one of them was mentioned by Dr. Morse just previously. That would be to allow the use of local or State governmental funds to purchase vaccines off the Federal contract. We have proposed this to the manufacturers. They have not as yet accepted it.

Now, the procedure for purchasing vaccines begins with our request from the State health departments as to what they anticipate their needs will be for vaccines in the coming 12-month period.

Senator HAWKINS. That is a request you make of all the States?

Dr. HINMAN. That is correct.

Senator HAWKINS. Does that go out at a fixed date?

Dr. HINMAN. I am sorry?

Senator HAWKINS. What date does that go out? Is there a set time for it?

Dr. HINMAN. It just went out for this year. So, this year, it went out in July. It has to do with our planning in the budget cycle. After we get the estimates in from the States as to what they project their needs will be for vaccine to be purchased under the contract, we then make minimum and maximum estimates as to the amount of vaccine which will be purchased, and prepare a request for a contract to obtain price information from the manufacturers.

The negotiations for the contract are carried out by two different offices. The Veterans' Administration handles the negotiations for the contract for measles, mumps, and rubella vaccines, and CDC directly negotiates the contracts for all polio vaccine.

Senator HAWKINS. Do you consider low vaccine prices a key to the success of the national immunization effort?

Dr. HINMAN. Low vaccine prices have certainly been an important factor in our ability to use the funds available to us.

Senator HAWKINS. Do you believe that as prices skyrocket, the number of children immunized goes down?

Dr. HINMAN. Well, Senator, I think the last chart over on the right there that shows the purchase trends is a reflection of the major effort that went on in the period 1977 through 1980–81 in the childhood immunization initiative.

As you will recall, we estimated that there might be as many as 20 million children who needed immunizations. So, the major increase in purchases of vaccine in 1977 and then in 1978 over the previous pattern reflected the beginning efforts to reach this backlog.

We would project that there would be a decrease in the amount of vaccine to be administered as we reduce this backlog.

Senator HAWKINS. Did you not say at our last hearing that as the prices increase, you expected a decrease in the number of children that would be immunized?

Dr. HINMAN. There are intertwining factors, Senator. First of all, there is a decrease in the number of children who need to be immunized. Secondly, it is clear that with a stable level of funding, as prices go up one can afford to buy fewer doses of vaccine. That has to be recognized.

However, there are mechanisms other than the categorical grant mechanism for providing vaccine for children through the public sector. One of them is local and State funding; another is the use of other Federal funds to purchase through the Federal contract.

Senator HAWKINS. When we had our hearing in May, you asked us to ask the manufacturer why the costs were increasing so much. We have done that here today. But is it not incumbent on the CDC, as the director and manager of this Nation's immunization effort, to investigate and address any threat to this vital mission?

Dr. HINMAN. Yes. In answer to your question, I guess my response is what threat specifically are you talking about now, the possibility that a manufacturer might leave the marketplace or——

Senator HAWKINS. Cost increases.

Dr. HINMAN. Senator, our leverage on negotiating our prices on vaccines is extremely limited because of the fact that there is a single manufacturer for these vaccines.

Senator HAWKINS. Sole source; we discovered that this morning.

Dr. HINMAN. I believe, though, that in contract terms this is not a sole-source contract but a competitive procurement, because there is more than one licensed manufacturer, for example, for some of the products. It is not negotiated as a sole-source contract.

Solicitations go out; there has been only one response. But it is just an issue of the term "sole-source contract."

Senator HAWKINS. Would you be surprised if you got two?

Dr. HINMAN. I would be, yes, because Pfizer, which has a license to produce polio vaccine in this country, has not produced or sold in this country for the last 5 years. And there is, to my knowledge, no other manufacturer of measles, mumps, and rubella, in combination, in the world at the present time. Certainly, there is no other licensed in the United States.

Senator HAWKINS. The statute governing this immunization effort says, in part, that States shall provide adequate reporting "to assure the proper disbursement of and accounting for funds received under grants."

[The material referred to follows:]

[Excerpt from Vol I--Title III of Compilation of Selected Acts Within the Jurisdiction of the Committee on Energy and Commerce]

PROJECT GRANTS FOR PREVENTIVE HEALTH SERVICES

SEC. 317. [247b] (a) The Secretary may make grants to States, and in consultation with State health authorities, to political subdivisions of States and to other public entities to assist them in meeting the costs of establishing and maintaining preventive health service programs.

(b) No grant may be made under section (a) unless an application therefor has been submitted to, and approved by, the Secretary. Such an application shall be in such form and be submitted in such manner as the Secretary shall by regulation prescribe and shall provide—

(1) a complete description of the type and extent of the program for which the applicant is seeking a grant under subsection (a);

(2) with respect to each such program (A) the amount of Federal, State, and other funds obligated by the applicant in its latest annual accounting period for the provision of such program, (B) a description of the services provided by the applicant in such program in such period, (C) the amount of Federal funds needed by the applicant to continue providing such services in such program, and (D) if the applicant proposes changes in the provision of the services in such program, the priorities of such proposed changes, reasons for such changes, and the amount of Federal funds needed by the applicant to make such changes;

(3) assurances satisfactory to the Secretary that the program which will be provided with funds under a grant under subsection (a) will be provided in a manner consistent with the State health plan in effect under section 1524(c) and in those cases where the applicant is a State, that such program will be provided, where appropriate, in a manner consistent with any plans in effect under an application approved under section 315;

(4) assurances satisfactory to the Secretary that the applicant will provide for such fiscal control and fund accounting procedures as the Secretary by regulation prescribes to assure the proper disbursement of and accounting for funds received under grants under subsection (a);

(5) assurances satisfactory to the Secretary that the applicant will provide for periodic evaluation of its program or programs;

(6) assurances satisfactory to the Secretary that the applicant will make such reports (in such form and containing such information as the Secretary may by regulation prescribe) as the Secretary may reasonably require and keep such records and afford such access thereto as the Secretary may find necessary to assure the correctness of, and to verify, such reports;

(7) assurances satisfactory to the Secretary that the applicant will comply with any other conditions imposed by this section with respect to grants; and

(8) such other information as the Secretary may by regulation prescribe.

(c)(1) The Secretary shall not approve an application submitted under subsection (b) for a grant for a program for which a grant was previously made under subsection (a) unless the Secretary determines—

(A) the program for which the application was submitted is operating effectively to achieve its stated purpose,

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(B) the applicant complied with the assurances provided the Secretary when applying for such previous grant, and

(C) the applicant will comply with the assurances provided with the application.

(2) The Secretary shall review annually the activities undertaken by each recipient of a grant under subsection (a) to determine if the program assisted by such grant is operating effectively to achieve its stated purposes and if the recipient is in compliance with the assurances provided the Secretary when applying for such grant.

(d) The amount of a grant under subsection (a) shall be determined by the Secretary. Payments under such grants may be made in advance on the basis of estimates or by the way of reimbursement, with necessary adjustments on account of underpayments or overpayments, and in such installments and on such terms and conditions as the Secretary finds necessary to carry out the purposes of such grants.

(e) The Secretary, at the request of a recipient of a grant under subsection (a), may reduce the amount of such grant by—

(1) the fair market value of any supplies (including vaccines and other preventive agents) or equipment furnished the grant recipient, and

(2) the amount of the pay, allowances, and travel expenses of any officer or employee of the Government when detailed to the grant recipient and the amount of any other costs incurred in connection with the detail of such officer or employee.

when the furnishing of such supplies or equipment or the detail of such an officer or employee is for the convenience of and at the request of such grant recipient and for the purpose of carrying out a program with respect to which the grant under subsection (a) is made. The amount by which any such grant is so reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies or equipment, or in detailing the personnel, on which the reduction of such grant is based, and such amount shall be deemed as part of the grant and shall be deemed to have been paid to the grant recipient.

(f)(1) Each recipient of a grant under subsection (a) shall keep such records as the Secretary shall by regulation prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such grant, the total cost of the undertaking in connection with which such grant was made, and the amount of that portion of the cost of the undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(2) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipient of grants under subsection (a) that are pertinent to such grants.

(g)(1) Nothing in this section shall limit or otherwise restrict the use of funds which are granted to a State or to an agency or a political subdivision of a State under provisions of Federal law (other than this section) and which are available for the conduct of preventive health service programs from being used on connection with programs assisted through grants under subsection (a).

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(2) Nothing in this section shall be construed to require any State or any agency or political subdivision of a State to have a preventive health service program which would require any person, who objects to any treatment provided under such a program, to be treated or to have any child or ward treated under such program.

(h) The Secretary shall include, as part of the report required by section 1705, a report on the extent of the problems presented by the diseases and conditions referred to in subsection (j) on the amount of funds obligated under grants under subsection (a) in the preceding fiscal year for each of the programs listed in subsection (j); and on the effectiveness of the activities assisted under grants under subsection (a) in controlling such diseases and conditions.

(i) The Secretary may provide technical assistance to States, State health authorities, and other public entities in connection with the operation of their preventive health service programs.

(j)(1) For grants under subsection (a) for preventive health service programs to immunize children against immunizable diseases there are authorized to be appropriated $29,500,000 for the fiscal year ending September 30, 1982, $32,000,000 for the fiscal year ending September 30, 1983, and $34,500,000 for the fiscal year ending September 30, 1984.

(2) For grants under subsection (a) for preventive health service programs for tuberculosis there are authorized to be appropriated $9,000,000 for the fiscal year ending September 30, 1982, $10,000,000 for the fiscal year ending September 30, 1983, and $11,000,000 for the fiscal year ending September 30, 1984.

Senator HAWKINS. Are you receiving reports from each State?

Dr. HINMAN. We receive annual reports on expenditures under the grants from our grantees, yes.

Senator HAWKINS. Are they being analyzed by your staff?

Dr. HINMAN. In the Immunization Division, we do not do the detailed financial analysis. That is done in the Office of Resource Analysis.

Senator HAWKINS. The resource analysis office does the analysis of the reports?

Dr. HINMAN. Right.

Senator HAWKINS. What about the disturbing reports we heard today regarding New York? Is this a problem that the CDC should have corrected?

Dr. HINMAN. I believe, Senator, that the legislation and regulations apply to the use of the grant funds, and do not apply to responsibilities for reporting on the use of State funds.

Senator HAWKINS. Was there a Federal CDC employee in Florida in 1977?

Dr. HINMAN. Yes.

Senator HAWKINS. 1978?

Dr. HINMAN. Yes, there was.

Senator HAWKINS. And 1979?

Dr. HINMAN. Yes.

Senator HAWKINS. Is there a Federal CDC employee in New York?

Dr. HINMAN. Yes; there are three.

Senator HAWKINS. There are three?

Dr. HINMAN. Yes.

Senator HAWKINS. Have those employees reported these costs to the CDC?

Dr. HINMAN. The State vaccine costs?

Senator HAWKINS. Yes.

Dr. HINMAN. Yes, they have.

Senator HAWKINS. How could Florida and New York have paid extra for polio and MMR while a CDC employee worked in their midst? Take Florida separate from New York.

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Dr. HINMAN. Would you rephrase the question?

Senator HAWKINS. Why, in your estimation, were they not using CDC funds to purchase the MMR plus polio vaccines?

Dr. HINMAN. There are a variety of reasons why States might not use the grant funds to purchase all of their vaccines. These include the fact that it is easier, quite frankly, to get State dollars from State legislatures to buy vaccine than it is to buy the people who control disease and investigate its occurrence.

They include the fact that in some States—for example, in Alaska, it has been the opinion of the Alaska attorney general that the carrying out of the duty to warn, which is a contractual obligation in buying the vaccines, does not require having a signature on the important information form. Consequently, Alaska chooses to buy the vaccine using State funds, so they can carryout the notification of risks and benefits by means other than that which we require.

Dr. King testified, as you will recall, that one of the reasons that Florida delayed in making a switch over to federally provided vaccines was their concern about implementing our warning process.

Senator HAWKINS. Since we found problems in two of the seven States that we had time to examine, do you have any idea how many others are likely to be experiencing the same problem?

Dr. HINMAN. Which specific problem, Senator?

Senator HAWKINS. Inefficient purchasing procedures.

Dr. HINMAN. Nationwide, Senator, about half of the grant funds are used to purchase vaccine. The remainder is used primarily to support personnel in the investigation and surveillance of disease.

Senator HAWKINS. Fifty-fifty?

Dr. HINMAN. Just about. It is a little bit less than 50 percent, I think, this year.

Senator HAWKINS. Mr. Stenhouse, I believe in your statements to the staff you said that you are not in a good position to demand lower prices and you are somewhat hamstrung in your negotiations. Is that because of the sole source?

Dr. HINMAN. That certainly limits one's ability.

Senator HAWKINS. Dr. Hinman, have you been informed of the 1982 prices for MMR?

Dr. HINMAN. Yes, I have.

Senator HAWKINS. Could you give us——

Dr. HINMAN. The 1982 contract price for MMR vaccine in the United States under the Federal contract, Senator, is shown in table 3 of our prepared testimony, and it is $4.50 a dose in a single-dose container.

Senator HAWKINS. Do you have them for 1983?

Dr. HINMAN. No, we do not.

Senator HAWKINS. Do you have them for polio?

Dr. HINMAN. For 1982, our current contract price is 58.2 cents per dose—a contract that just recently went into effect.

Senator HAWKINS. An increase of 10 cents?

Dr. HINMAN. I am sorry?

Senator HAWKINS. An increase of 10 cents?

Dr. HINMAN. That is correct.

Senator HAWKINS. In your opinion, what can the Senate do to assure the best possible prices are received on these vaccines so

that the maximum number of children can be immunized? After all, that is the thrust of the immunization program.

Dr. HINMAN. I think it is difficult to try to speculate on a single action that the Senate might take. I think the manufacturers might feel that one important thing would be to exempt them from their liability concerns.

Senator HAWKINS. To exempt them from their liability?

Dr. HINMAN. Their liability concerns.

I think an important ability to get more for our money in the vaccination business would be something that probably does not require Senate action, and that would be to permit the use of local and State funds to purchase vaccines under the Federal contract.

I would speculate, Senator, that the fact of this hearing may help promote that cause.

Senator HAWKINS. I would hope so. We have several thoughts on legislation that may also be helpful.

[The prepared statement of Dr. Hinman follows:]

STATEMENT

BY

DR. ALAN R. HINMAN

DIRECTOR

IMMUNIZATION DIVISION

CENTER FOR PREVENTION SERVICES

CENTERS FOR DISEASE CONTROL

BEFORE THE

SUBCOMMITTEE ON INVESTIGATIONS AND GENERAL OVERSIGHT
COMMITTEE ON LABOR AND HUMAN RESOURCES

UNITED STATES SENATE

WASHINGTON, D.C.

JULY 22, 1982

I am pleased to be here to discuss with you the role of the Federal Government in purchasing and distributing vaccines for use in childhood immunization programs. As Dr. Foege testified in his appearance before this Subcommittee on May 7, 1982, the "widespread use of vaccines in childhood has had a major impact on the occurrence of disease in this country. Continued use of vaccines is necessary in order to maintain the excellent progress that has been made to date."

As Dr. Foege also testified in his earlier appearance, we estimate that approximately one-half of all children in the United States receive their routine immunizations in the public sector, primarily in local health department clinics. A grant program, administered by the Centers for Disease Control, provides assistance to State and local health departments in carrying out childhood immunization programs. I would now like to review briefly the history of Federal involvement in immunization programs and vaccine procurement.

Active Federal support of immunization programs began in Fiscal Years 1956 and 1957 when a total of $53.6 million in Federal grant assistance was provided to States for the conduct of inactivated polio vaccine (Salk vaccine) programs. The Federal Government itself did not purchase the vaccine; vaccine was purchased by States and communities using the Federal grant funds. In 1961, following the licensure of monovalent oral polio vaccine (Sabin vaccine), an epidemic stockpile of monovalent oral polio vaccine was established at the Federal level using a one-time appropriation of $1 million. During Fiscal Years 1961 and 1962, several million doses of monovalent oral polio vaccines were purchased by the Federal Government and provided to States and communities for epidemic aid.

In 1962, the Vaccination Assistance Act was passed, and in 1963 the Federal Government began to provide assistance to States and communities in the conduct of intensive vaccination programs, primarily using oral polio vaccine (OPV). No direct Federal purchase of vaccine was made at that time. In August 1965, the legislative authority of the Vaccination Assistance Act was amended to include the administration of measles vaccine, and additional grant funds were made available for the purchase and widespread use of measles vaccine. In Fiscal Year 1966, for the first time, the Federal Government directly purchased vaccine under consolidated contracts and provided it to States and communities "in lieu of cash" in their immunization grants. Establishment of the consolidated Federal contracts permitted a substantial savings to be realized. Measles and polio vaccines were then directly provided to States and communities by the Federal Government "in lieu of cash" in their immunization grants.

Beginning in 1969, the Federal Government began to directly purchase rubella vaccine. In 1975, a consolidated contract was established for the purchase of combined measles-mumps-rubella vaccine, and in 1978 a contract was established for single antigen mumps vaccine. Thus, consolidated Federal contracts have now been established for the purchase of each of the live virus vaccines routinely administered to children in the United States. Consolidated Federal contracts for diphtheria and tetanus toxoids and pertussis vaccine, whether combined as DTP or in other combinations (DT or Td) have not been established to provide vaccines to States as a part of grant assistance because the price of this vaccine is so low it has been estimated that the price savings from establishing such contracts would probably not offset the costs of administering the distribution program.

In addition to the purchase of vaccines through the consolidated Federal contracts using immunization grant funds, beginning in 1972, an "optional use" clause was included in the vaccine contracts. This permits purchase of vaccine using Federal funds other than immunization grant funds, such as maternal and child health or prevention services block grant funds. Although we have proposed allowing the use of any governmental funds (whether Federal, State, or local) to purchase vaccines through the consolidated contracts, to date the manufacturers have agreed only to the use of other Federal funds.

Thus, grantees may receive vaccines through three procurement mechanisms. The primary source for live virus vaccines is the use of the consolidated Federal contracts. The grantees order and receive vaccines from these contracts in lieu of immunization grant funds. The second method is through the optional use provision, under which grantees may order vaccine directly from the contractors provided the grantees use Federal funds (other than immunization grant funds). Vaccines are delivered to the grantee at the prices contained in the Federal contracts. The third mechanism is when grantees do not use Federal funds, but use their own purchasing systems to purchase vaccines.

The procedure used for establishing consolidated Federal contracts is initiated by obtaining estimates of annual vaccine requirements from grantees. Specifications are then prepared which evolve into a request for contract. The request for contract establishes the minimum and maximum amount of vaccines to be ordered during a 12-month period. Vaccine manufacturers then prepare their offers including prices of vaccine. The offers are

evaluated and, if required, negotiations are conducted to discuss or clarify any aspect of the offers. A final contract is then developed and signed by the manufacturers and the Government.

The contracting functions are carried out by two contracting offices. In the case of the measles, mumps and rubella vaccines, the Veterans Administration, Marketing Division, Pharmaceutical Products (Hines, Illinois) conducts the procurement and awards the contract. During this process, close liaison is maintained between the Veterans Administration and the Centers for Disease Control. In the case of oral polio vaccine, the Procurement & Grants Office, Centers for Disease Control, conducts the procurement. Since the Veterans Administration awards Federal Supply Schedule contracts for measles, mumps, and rubella vaccines for use by other Executive Agencies, the VA also procures these vaccines on behalf of CDC. Since there is no Federal Supply Schedule contract for oral polio vaccine, the Centers for Disease Control conducts and awards a contract for that vaccine.

Vaccine prices are generally evaluated using two guidelines. Prices are compared with past prices in terms of percent of change. Prices are also compared with current published commercial and existing Federal supply schedule price lists. The manufacturers contract prices are substantially less than the published commercial or Federal supply schedule prices .

Currently, there are only two manufacturers providing vaccines through the Federal contracts: (1) Merck, Sharp and Dohme, and (2) Lederle. Merck, Sharp and Dohme is the only current manufacturer of measles, mumps and rubella vaccines in the United States. Lederle Laboratories is the only current manufacturer of oral polio vaccine in the United States. Contracts have been awarded annually for the past 5 years without any lapse or disruption to supply of vaccines.

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Beginning in 1976, Federal contracts for the purchase of vaccines have included, at the manufacturers' insistence, a requirement that the Federal Government assume the "duty to warn" vaccine recipients of the risks as well as the benefits of vaccination. The Federal Government in turn transfers this "duty to warn" to the grantees and specifies the mechanism by which the warning shall be carried out and documented. This is through the use of "Important Information Forms". These forms must be used in all settings where federally purchased vaccine is used, unless the vaccine is used by a private physician. Private physicians are allowed to use individualized medical judgment instead of using the Important Information Forms in deciding whether or not to administer a federally purchased vaccine.

I would now like to discuss the extensive use of the Federal consolidated contract. Table 1 shows the proportion of the total National vaccine distribution which was purchased under consolidated Federal contracts in the 5-year period 1977-1981. Some initial explanations should be given. The data on National vaccine distribution are obtained from reports voluntarily submitted by vaccine manufacturers to the Centers for Disease Control as part of our Biologics Surveillance Program. They represent net vaccine distribution, that is, the total distribution of vaccine (both civilian and military) less the recorded returned doses of vaccine. The second note is that the data for total vaccine distribution represent calendar year data whereas the data for Federal contract purchases represent Federal fiscal year data. Consequently, these two data sets are not entirely comparable but, since they represent a 5-year summary, they give a good approximation of the total proportion of National vaccine distribution which is purchased under

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consolidated Federal contracts. Finally, it should be noted that the vaccines listed represent all formulations containing a specific antigen. For example, the category of measles vaccine includes the total number of doses of vaccine distributed which contain measles antigen, whether as single measles vaccine, combined measles-rubella vaccine (M/R), or combined measles, mumps, rubella vaccine (MMR).

Reflecting the fact that no Federal consolidated contracts have been established for DTP or DT vaccines, none of this vaccine was purchased through Federal contracts. In the past 5 years, 32 percent of oral polio vaccine, 44 percent of rubella-containing vaccines, 47 percent of measles-containing vaccines, and 50 percent of mumps-containing vaccines distributed in the United States were purchased under the consolidated Federal contract.

Table 2a shows the proportion of vaccines used in the public sector which was purchased under the Federal Contracts. Table 2b shows the proportion of vaccines purchased under the Federal Contracts using Federal Immunization Grant Funds compared to Other Federal Funds (using the optional use clause). As shown in Table 2a more than 95 percent of the measles, mumps, and rubella-containing vaccines used in the public sector were purchased under the Federal Contract; a somewhat smaller proportion of the oral polio vaccine used in the public sector is purchased through the Federal Contract (87%). As shown in Table 2b, Federal Immunization Grant Funds accounted for approximately 85 percent of all Federal Contract purchases.

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Table 3 shows the cost per dose of vaccines purchased under consolidated Federal contracts from Fiscal Year 1971 to the present time. Table 4 compares the prices in Fiscal Year 1977 with those at present and shows the percent change over this 6-year period. The price increases range from 86 percent for MMR vaccine to 168 percent for rubella vaccine during that 6-year period.

Table 5 compares retail prices for selected vaccines as listed by the manufacturers in July 1982, State contract prices as reported in an informal survey of State health departments carried out in April 1982, and current Federal contract prices. It is clear that there is a substantial savings afforded by purchasing vaccines under State contracts as opposed to purchasing them at the retail catalog price and that further savings are achieved by purchasing vaccines under the consolidated Federal contract rather than at the State prices.

In the 5 years Fiscal Year 1977 through Fiscal Year 1981, nearly 87 million doses of vaccine have been purchased through the consolidated Federal contracts. Many of these were purchased in multi-dose, rather than single dose vials. If these vaccines had been purchased in single dose vials (except for OPV in 10 dose vials) at the retail catalog price extant in each of those years they would have cost in total approximately $162 million. The total cost of these vaccines was approximately $56 million, of which $47 million came from immunization grant funds; the remainder came from other Federal funds.

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Thus a savings of more than $100 million has been realized over the last 5 years as a result of the purchasing of vaccines through consolidated Federal contracts. This indicates why we feel the consolidated contracts are an important part of the Federal Government's role in supporting childhood immunization programs.

I would be happy to try to answer any questions you may have.

TABLE 1

PROPORTION OF NATIONAL VACCINE
DISTRIBUTION PURCHASED UNDER
CONSOLIDATED FEDERAL CONTRACTS
FY 1977-FY 1981

VACCINE	TOTAL DISTRIBUTION (DOSES)*	FEDERAL CONTRACT PURCHASES (DOSES)	FEDERAL CONTRACT PURCHASES AS PERCENT OF TOTAL DISTRIBUTION
DTP/DT	98,065,912	-	-
OPV	118,861,075	38,295,440	32.2
Measles	42,709,993	20,092,475	47.0
Mumps	25,468,613	12,936,925	50.8
Rubella	35,455,981	15,668,955	44.2

*Calendar Year

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TABLE 2a

COMPARISON OF TOTAL PUBLIC SECTOR VACCINE USE (DOSES)
WITH CONSOLIDATED FEDERAL CONTRACT PURCHASES (DOSES)
U. S. A. FY 1977-FY 1981

VACCINE	TOTAL PUBLIC SECTOR USE (DOSES)	TOTAL FEDERAL CONTRACT PURCHASES (DOSES)	FEDERAL CONTRACTS AS PERCENT OF TOTAL PUBLIC SECTOR USE
OPV	44,094,831	38,295,440	86.8
Measles	19,240,169	20,092,475*	104.4
Mumps	13,214,076	12,936,925	97.9
Rubella	15,089,125	15,668,955*	103.8

*In these instances, total Federal contract purchases exceed total public sector doses, possibly because of vaccine wastage or stockpiling of vaccine.

TABLE 2b
DISTRIBUTION OF TOTAL FEDERAL PURCHASES (DOSES):
FEDERAL IMMUNIZATION GRANT FUNDS AND OTHER FEDERAL FUNDS,
U.S.A. FY 1977-FY 1981

VACCINE	TOTAL FEDERAL CONTRACT PURCHASES (DOSES)	FEDERAL IMMUNIZATION GRANT FUNDS (DOSES)	PERCENT	OTHER FEDERAL FUNDS (DOSES)	PERCENT
OPV	38,295,440	31,809,020	83.1	6,486,420	16.9
Measles	20,092,475	17,373,745	86.5	2,718,730	13.5
Mumps	12,936,925	10,710,645	82.8	2,226,280	17.2
Rubella	15,668,955	13,367,365	85.3	2,301,590	14.7

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TABLE 3

PRICE PER DOSE OF SELECTED VACCINES
UNDER CONSOLIDATED FEDERAL CONTRACTS
FY 1971-FY 1982

YEAR	OPV*	MEASLES	MUMPS	RUBELLA	M/R	MMR
1971	-	$1.035	-	$0.61	$1.74	-
1972	-	1.082	-	0.57	1.78	-
1973	$0.108	1.035	-	0.57	1.74	-
1974	0.08	0.98	-	0.55	1.74	-
1975	0.15	0.85	-	0.58	1.17	$2.42
1976	0.186	0.71	-	0.60	1.19	2.42
1977	0.295	0.86	-	0.60	1.19	2.42
1978	0.313	0.87	1.40	0.71	1.20	2.55
1979	0.332	1.12	1.60	0.94	1.58	2.62
1980	0.354	1.15	1.63	0.97	1.64	2.71
1981	0.396	1.32	1.87	1.12	1.89	3.12
1982 early	0.475	1.70	2.41	1.44	2.43	4.02
current	0.582	1.90	2.70	1.61	2.72	4.50

*In 10 dose vials; all others in single dose vials

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TABLE 4

COMPARISON OF VACCINE PRICE PER DOSE
UNDER CONSOLIDATED FEDERAL CONTRACTS
1977 and 1982

VACCINE	1977	1982	PERCENT CHANGE
OPV*	$0.295	$0.582	+ 97
Measles	0.86	1.90	+121
Mumps**	1.40	2.70	+ 93
Rubella	0.60	1.61	+168
M/R	1.19	2.72	+129
MMR	2.42	4.50	+ 86

*In 10 dose vials; all others in single dose vials

**1978 price; no contract in 1977

TABLE 5

COMPARISON OF SELECTED
VACCINE PRICES PER DOSE
JULY 1982

VACCINE	CATALOG	STATE*	FEDERAL
DTP (15 dose vial)	$0.455**	$0.081-0.179	-
OPV (10 dose vial)	2.21	0.96 -2.08	$0.582
MMR (single dose vial)	10.44	6.84 -9.14	4.50

*Based on an informal survey of States in April 1982

**One manufacturer queried

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Senator HAWKINS. I would like to thank you for coming today and participating and for listening to the testimony that was given here. I hope that the discussion which has taken place will be constructive and will prove useful to achieve the strongest, most effective immunization program possible.

I remain deeply concerned, as does Senator Kennedy, about the cost of childhood vaccines posing a real threat to our immunization program. And even with the very best management and oversight at the State and Federal levels, we found today that we are still fighting an uphill battle to vaccinate all our children. Without the critical communication, the investigation, and the direction necessary to administer these programs, I still think we may be in grave danger.

We must learn the lessons provided by responsible international organizations, some of whom have testified here today, who have sought creative solutions to maintaining the key element of competition in the vaccine marketplace. Ours should be an attitude characterized by constant inquiry and examination of price variations and market conditions.

And though the immunization program is widely recognized as cost-effective, preventive medicine, we must not loosen our grip on obtaining a top-quality product at affordable prices. I really believe that the Centers for Disease Control is the appropriate agency to provide the overall direction for an aggressive campaign to keep these prices in check. I am considering legislation which will make clear the role of the CDC in combating those factors which threaten the immunization program. I am convinced that once advised of what we learned here today, the Senate will take appropriate action.

[The following information was received for the record:]

LEDERLE LABORATORIES

A Division of AMERICAN CYANAMID COMPANY
WAYNE, NEW JERSEY 07470
AREA CODE 201 831-1234

Jack Bowman
President

July 16, 1982

Honorable Paula Hawkins
United States Senate
Chairman, Subcommittee on Investigations
and General Oversight
Senate Committee on Labor and Human
Resources
4230 Dirksen Senate Office Building
Washington, D. C. 20510

Dear Senator Hawkins:

Please be advised that I will be present to testify at the public hearing on immunization costs before your Subcommittee on Investigations and General Oversight July 22, 1982 pursuant to your July 13, 1982 letter of invitation.

I will be accompanied by Dr. Francis R. Cano, who directs Lederle vaccine production and is expert concerning vaccine research.

We will make every effort to cooperate fully in the Committee's objective of developing an accurate understanding of the complex subject you wish to examine. Please find enclosed information relevant to your inquiry submitted for the record.

Sincerely,

Jack Bowman

J. Bowman

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Enclosure

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Lederle Vaccine History Highlights

Lederle Laboratories has had one of the longest and most diverse histories of any pharmaceutical company in the United States with vaccine development and production. The company was, in fact, started more than 70 years ago to produce diphtheria antitoxin which was a forerunner of the immunizing agent used today.

In the early 20th century, purified diphtheria antitoxin was imported from Germany, cost $12 a dose, and was scarce. To provide a plentiful, low cost domestic supply. Dr. Ernst J. Lederle, a former New York City Health Commissioner, founded the firm that still bears his name. In subsequent years Lederle produced and distributed in this country and other countries throughout the world a line of immunizing agents for cholera, tetanus, rabies, influenza, common measles, mumps, Rocky Mountain Spotted Fever, smallpox and typhus.

The oral polio vaccine is a singular and an historic achievement in medical science, and Lederle's very impressive contributions to the perfection of the oral polio vaccine deserves special mention and delineation. Research on attenuated live virus polio vaccine got under way at Lederle, shortly after World War II, in 1946. The Lederle work was in contra-distinction to the Salk polio vaccine which utilizes a killed virus. The obvious distinction to the lay public is that the killed virus vaccine must be injected. The attenuated live virus is taken orally.

In 1950, after four years' work, members of Lederle's polio research staff became the first persons to take an oral vaccine as a means of immunization from the polio virus, and none experienced any ontoward reactions to the vaccine and research work continued.

In 1957, two years after the Salk vaccine was introduced and, then, in wide use, Lederle's oral polio vaccine was tested on small groups of volunteers in New York, Minnesota, New Jersey, and California. Meanwhile, the vaccine was under study in 20 other countries worldwide. It was also during this period that Dr. Albert Sabin, of the University of Cincinnati, had begun his work in the development of oral polio vaccine strains.

Lederle and Sabin continued research and development separately along individual precepts previously established. In 1960, Lederle worked in cooperation with university scientists, medical societies, local government officials and community groups, in carrying out the first mass immunization program in a community. It was in Dade County (Miami), Florida, and more than a half million individuals volunteered to take the vaccine. Later, follow up studies showed a high level of immunization in Dade County against polio. Coincidentally, the Sabin oral polio vaccine was also being tested successfully.

Government officials decided, on the basis of their laboratory studies, and clinical investigations carried out mainly abroad, that at least one of the Sabin vaccine strains was preferable to the comparable Lederle strain. Lederle accepted the decision,

and, since it had extensive experience with oral polio vaccine, the company was exceptionally qualified to produce an oral vaccine from the Sabin strains. A license was granted shortly.

Lederle, from 1961 into 1963, worked with the three Sabin monovalent strains of vaccine and perfected a trivalent vaccine. In 1963 Lederle was licensed to produce the three-in-one oral polio vaccine. In other words, children had to swallow only one small dose of the Lederle vaccine, ORIMUNE®, in contrast to the monovalent form which required three administrations of vaccine on separate visits to the physician's office or clinic.

The Center for Disease Control, MMWR (Vol. 31/No.3 -- 1/29/82) reports the following figures: "In the 12-year period 1969-1980, approximately 290 million doses of OPV were distributed, and 92 cases of paralysis associated with vaccine were reported. Twenty-five cases of paralysis occurred in otherwise healthy vaccine recipients, 55 cases in health close contacts of vaccine recipients, and 12 cases in person (recipients or contacts) with immune-deficiency conditions."

In the period, 1950-54, before any polio vaccines were available, there were 28,000 cases of poliomyelitis each year.

The efficacy and safety record of the oral polio vaccine is, without question, without peer in the history of the use of immunizing agents.

Other Areas

Shortly after the laboratories was organized, Dr. Richard Slee, a recognized expert in smallpox, joined the organization. Soon, thereafter, smallpox vaccine production was changed to insure better controls, for safety and potenty of the vaccine. This was a great step forward and the principle was continued into the modern day.

Lederle's record during World War II was outstanding. The company was awarded the Army-Navy E Award for, among other achievements, producing: 33% of all typhus vaccine for the Armed Forces; 33% of the influenza virus vaccine; 40% of the Japanese B enecephalo vaccine. Lederle also developed and produced a line of vaccines for veterinary use, among them Anthrax spore vaccine, and rabies vaccine.

Lederle Vaccine Research

Since 1965 Lederle has invested more than $52M in current dollars in biologics research and development. (Prior to 1965 major investments were made in the development of the oral polio vaccine totalling some $16 million - more than $32M in current dollars - for this product alone.) The sums expended for such research over the past several years have remained fairly constant.

The amount allocated depends, to some extent, on what opportunities exist to make research advances. Lederle, at present, believes that certain basic research achievements have made several totally new areas of vaccine research well worth investigating. Moreover, we believe that fostering preventative medicine programs that include vaccines can help stem the upsurge in national health care costs.

Lederle has a number of active programs to develop new vaccine products. These programs are in various stages of development ranging from basic research to the last phases of clinical trials. An example of a research project that recently resulted in a new product is the development of the pneumococcal polysaccharide vaccine, PNU-IMUNE®. Pneumococcal pneumonia is the main cause of mortality that follows influenza epidemics, PNU-IMUNE is a broad spectrum vaccine effective against 14 capsular types accounting for at least 80% of all pneumococcal disease in the U. S.

Some other Lederle R & D programs to develop new vaccines include development of a haemophilus influenzae vaccine, which is currently in active clinical trials. The project has been identified as a high priority project by NIH. It is estimated that it will take at least 50 million dollars to develop the H-influenzae vaccine, and it will involve extensive efficacy studies in approximately 30,000 infants. Haemophilus influenzae is the main cause of acute bacterial meningitis. This infection results in the death of about 10 percent of those affected, many of them small children, and nearly half the survivors suffer long-term disability, including brain damage.

In addition, Lederle is working on development of a-cellular pertussis vaccine, and has most recently begun a research program for a herpes virus vaccine which is expected to cost at least $30 million.

An explanation of the costs of R & D is not complete without mention of the promising efforts which fail. For Lederle in the recent past these have included:

Product	R&D Cost	Investigation Period*
Respiratory Syncytial Virus	k$ 670	1966-1977
Human Infectious Hepatitis	1,400	1966-1976
Diploid Cell Polio	800	1972-1975
Neuraminidase Flu	4,300	1974-Present
Myxovirus	4,318	1966-1978

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Vaccine Production Difficulties

Vaccine production is very difficult because the products are derived from complex biological systems and invariably contain several components. For example, the pneumococcal polysaccharide vaccine, PNU-IMUNE®, contains 14 polysaccharides, each purified separately from the pathogenic strain of S. pneumoniae.

Vaccine manufacture requires growth of a bacteria or virus followed by extensive processing and testing before the product is released. In the example of PNU-IMUNE®, each polysaccharide isolated from the bacteria requires a series of 10-15 purification steps before the polysaccharide is of acceptable quality. Toxoids such as tetanus and diphtheria, also involve the purification of these proteins after the toxin has been produced by the bacteria and chemically inactivated to a toxoid. Viral vaccines require two phases of growth, that is, cell cultures must first be satisfactorily grown before they can be infected by the parasitic virus.

The materials are generally labile throughout the manufacturing process hence temperature and pH, among other variables, must be carefully controlled and monitored. Storage conditions require the same meticulous care. All the intermediates of ORIMUNE® as well as the final product are stored at or below -20°C. All the other vaccines are at least stored at refrigeration temperature. In addition, these materials are often pathogenic or toxic at some stage of manufacture. Therefore, production facilities must provide for adequate containment of the pathogens, and the production personnel must have a high level of technical training and competence.

Raw materials needed for vaccine production can be difficult to obtain and variable in quality. A prime example are the monkeys used in ORIMUNE® production and testing. Monkey supply has fluctuated widely in the last five years.

Prescreening of monkeys can eliminate as many as half of the animals available for purchase at any given time. Rhesus monkeys needed for testing have been a critical problem since India banned their export in 1978. Other countries can not meet the demand for animals. One new source being considered is China; however, recent experiments indicate that the animal may be sufficiently different to preclude its use. Other raw materials such as calf serum and medium components for bacteria have been difficult to obtain due to fluctuating markets and a limited number of manufacturers.

In addition to the biological nature of the production processes, it must be remembered that the assays used to determine safety and potency are usually biological and subject to the variations and long testing periods of such systems. One neurovirulence test for ORIMUNE® averages 4-5 months during which a trained pathologist reads histological sections from the nervous system of 50 animals. Pertussis potency is a mouse test, requiring about five weeks.

In appreciation of the complex nature of vaccine production and testing, Federal regulations are quite stringent. In most cases, a product is tested by both the manufacturer and the FDA prior to release. The FDA also releases several intermediates for further production. Two examples of this are the three types of polio monopools that are used to make ORIMUNE® bulk, and the 14 types of polysaccharide powders that are used in PNU-IMUNE®. Each lot of PNU-IMUNE® must meet the requirements of over 100 different tests before it can be released.

As can be seen from the above overview of vaccine production, the lead times for such products are very long. It typically requires 15-18 months to produce a lot of poliovirus vaccine. A large commitment must also be made to scientific development so that the appropriate expertise is available to respond to production problems and keep abreast of current technology.

Vaccines Currently Manufactured by Lederle

Poliovirus Vaccine, Live, Oral, Trivalent, ORIMUNE® - Sabin Strains, Types 1, 2 and 3.

Cholera Vaccines (India Strains)

TRI-IMMUNOL® Diphtheria and Tetanus Toxoids and Pertussis Vaccines, Adsorbed.

Tetanus and Diphtheria Toxoids Adsorbed, PUROGENATED® (for Adult use)

Diphtheria and Tetanus Toxoids Adsorbed, PUROGENATED® (for Pediatric use)

Tetanus Toxoid, PUROGENATED®

Tetanus Toxoid Adsorbed, PUROGENATED®

Pneumococcal Vaccine Polyvalent, PNU-IMUNE®

Merck, Sharp and Dohme Visual aids

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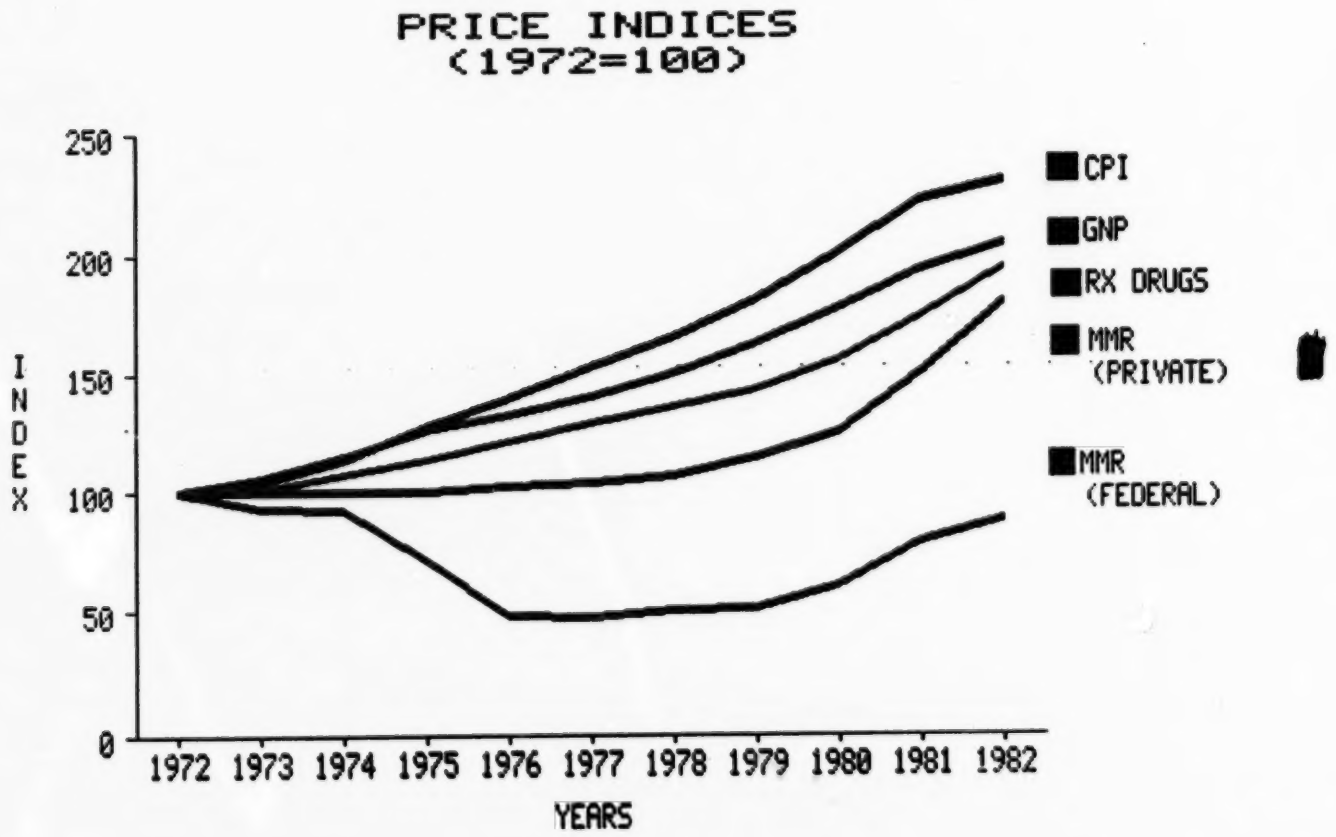

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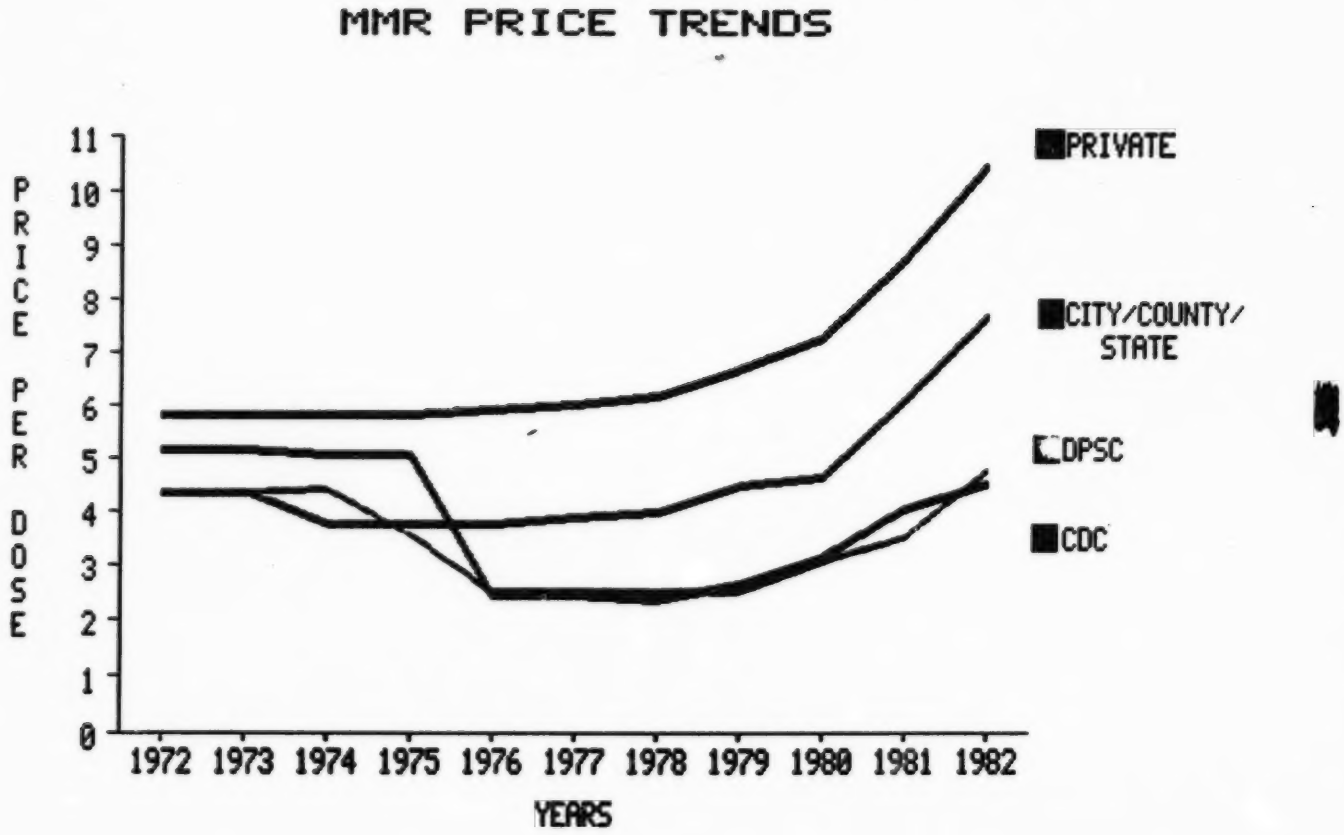

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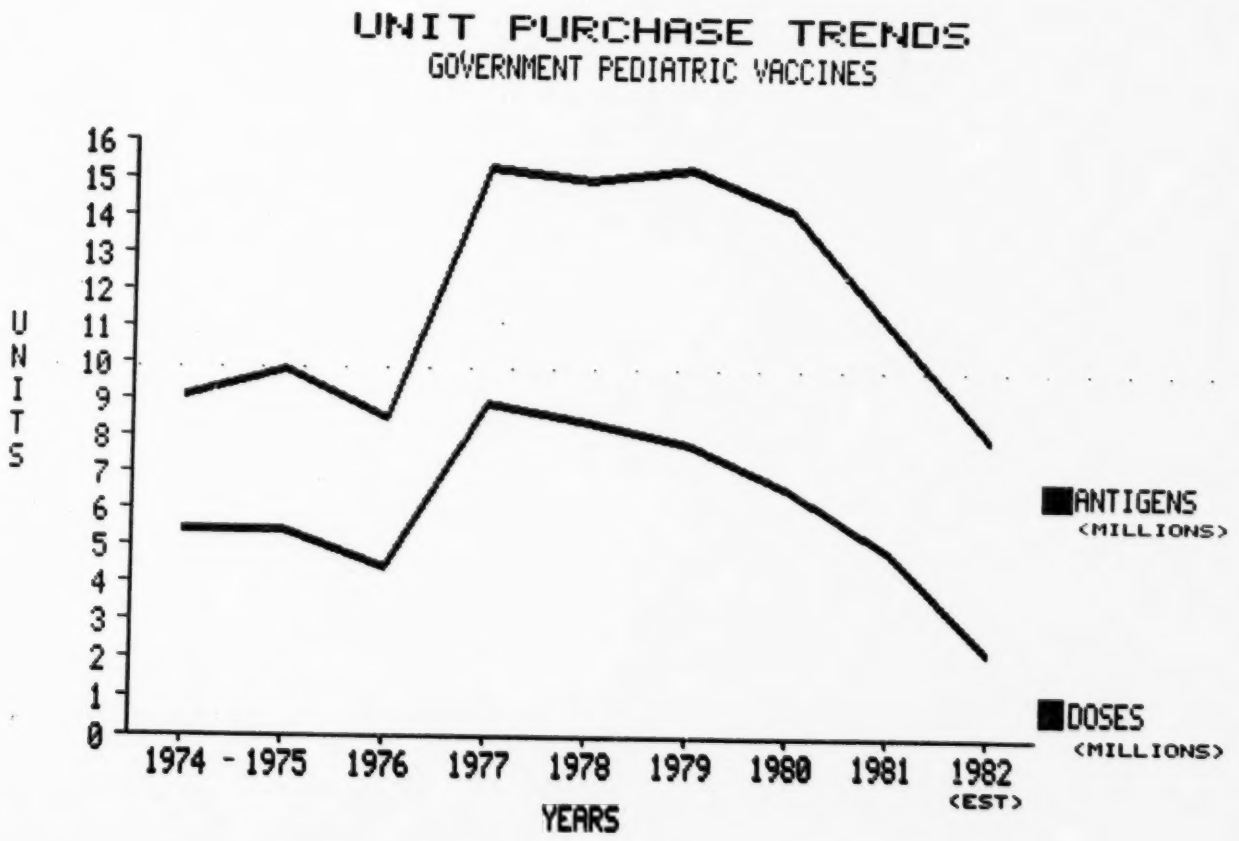

Captions for Charts:

#1 - Price Indices

Increases in prices charged the government and physicians for Merck's combined measles, mumps and rubella vaccine have lagged the Consumer Price Index, the Gross National Product deflator and the Firestone Index, a measurement of U.S. prescription drug prices, since 1972.

#2 - Price Trends

Prices charged the federal government for Merck's combined measles, mumps and rubella vaccine have been substantially lower than prices charged other purchasers for the last 10 years . Except during the period 1975-1976, when the CDC's Immunization Initiative program resulted in substantial increases in vaccine purchases, price trends in all sectors have followed comparable patterns.

#3 - Purchase Trends

Government purchases of both doses (combination vaccine) and antigens (protective units against individual diseases) have declined substantially dince 1977.

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Senator HAWKINS. We thank you for your participation. The hearing is adjourned.

[Whereupon, at 1:05 p.m., the subcommittee was adjourned.]

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